



A DUE PROCESS FOR BIOETHICS

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A DUE PROCESS FOR BIOETHICS

Introduction

On June 26, 2000, President Clinton announced on the White House lawn that a consortium of government-funded and private sector scientists had completed a working draft of the human genome sequence,¹ hailing it as “the most important, most wondrous map ever produced.”² Indeed, this achievement was a watershed moment in the history of humanity, the culmination of thousands of years of man’s efforts to better understand himself. Several millenia ago, Aristotle postulated that “humors” accounted for variations in people’s health and temperament, and since then, scientists have struggled relentlessly to comprehend how the human body works. By mapping the genome, scientists have identified the basic units of individual uniqueness and the blueprint for human development. As Francis Collins, the director of the NIH Human Genome Project, said at the White House ceremony, “We’re here to celebrate a milestone along a truly unprecedented voyage into ourselves... [the sequence is] a first glimpse of the instruction book previously known only to God.”³

This announcement also marked the beginning of what is likely to be an era of unprecedented progress in the biological sciences. The genomic sequence is not only a tremendous scientific achievement, but also a powerful tool to drive further inquiry. The sequence will allow scientists to probe more deeply and precisely into the workings of the human body and mind, from the predisposition for baldness to the basis of addictive behavior. The genomic sequence will also enable the development of novel techniques to diagnose and

¹The entire sequence is not yet complete; however, the “working draft” announced on this day included more than 90% of known genes and 95% of the genes known to cause disease. The NIH Human Genome Project intends to map the entire genome with 99.99% accuracy by 2003, and Celera Genomics has already assembled sequences from five DNA donors into a map which encompasses 99% of the 23 human chromosomes.

²Scott Hensley & Sarah Lueck, *Data Will Help Scientists Locate Specific Genes, Speed Cures for Disease*, WALL ST. J., June 27, 2000, available in 2000 WL-WSJ 3034414.

³*Id.*

cure disease, from “gene chips” which identify the presence of risky genes, to gene therapies which alter or counteract disease-causing genes. With the genome map, drug development can be much more systematic and efficient vis-à-vis the trial-and-error methodologies used today, and the resulting drugs can target the underlying causes of disease more specifically, rather than merely the symptoms. More generally, the genomic sequence will empower scientists to conduct research in only a fraction of the time that it previously required. A researcher can now “[chase] down genes at such a rate that what once took researchers years can now be finished before lunch.”⁴ In sum, the genome has unleashed – and will continue to yield – knowledge that will enable biomedical science to deliver tremendous benefits to society.

Furthermore, biomedical science is advancing at a remarkable pace. According to a researcher at MIT’s Whitehead Institute for Biomedical Research, “Whole new fields of biology are opening up right now, as we speak, and we don’t even know what they are yet.”⁵ It has become fairly routine to see front-page newspaper headlines heralding scientific advances, from the identification of a new cancer gene to the cloning of human embryos. These innovations are not only occurring quickly, but are also pushing the limits of what was traditionally regarded as feasible. For example, in reference to a company’s recent announcement of its latest breakthrough, the editor-in-chief of *Scientific American* magazine commented, “That is an amazing accomplishment in its own right, and like cloning, something that people once thought was impossible in mammals.”⁶

⁴Matt Crenson, *Progress Made on Human Genetic Code*, AP ONLINE, June 27, 2000, available in 2000 WL 23360202.

⁵*Id.*

⁶*U.S. Company Says It Cloned Human Embryo for Cells*, N.Y. TIMES.COM, Nov. 25, 2001. John Rennie, the editor-in-chief of *Scientific American* magazine, was reacting to the announcement by a biotechnology company (Advanced Cell Technologies) that it had successfully prompted a human egg cell to develop into an embryo without any kind of fertilization by outside genetic material, a process called parthenogenesis.

The pace of biomedical advances is only likely to increase as pressure mounts on the scientific community, not only from patients with serious illnesses, but also from investors who are banking on biotechnology as a profitable growth engine. The power of patients and their vocal advocates must not be underestimated. One only needs to look at the influential board members and financial coffers of groups such as the American Cancer Society and Juvenile Diabetes Foundation to realize that these groups have tremendous resources to push for further exploration of potential therapies. Patient advocacy groups also have a track record of molding policy to advance their objectives, as evidenced by successful efforts to expedite FDA review of AIDS drugs and secure a “compassionate use” exception for terminally ill patients in experimental trials.

Commercial pressures will also push scientists and biotechnology companies to quicken the speed of biomedical innovation. The financial attractiveness of the biotechnology sector is based on the expectation that scientists will be able to translate knowledge about the human genome into drugs and other treatments for devastating chronic diseases.⁷ A study by University of Chicago researchers estimated that a cure for cancer could be worth \$47 trillion in the United States alone.⁸ The demographic trend of a burgeoning aging population further enlarges the potential market for these biotechnological products.⁹ Investors have therefore been willing to inject large amounts of money into the biotechnology sector. Over 300 biotechnology companies have gone public on the stock exchange,¹⁰ and the market capitalization of the biotechnology industry increased more than 150% between 1999 to 2000, from \$138 billion to \$354 billion.¹¹ Because investors demand high returns on their investments, they will compel scientists and biotechnology companies to push the development of biomedical products more quickly and in the most commercially promising directions.¹²

⁷Michael Liedtke, *Genome Map May Spur Biotech Interest*, AP ONLINE, June 27, 2000, available in 2000 WL 23360269.

⁸*Id.* This study was conducted by University of Chicago researchers Bob Topel and Kevin Murphy.

⁹*Id.* The World Health Organization estimates that the number of people over 65 years old will grow from 550 million in 1998 to over 1 billion in 2020.

¹⁰*Id.*

¹¹Biotechnology Industry Organization, <www.bio.org/er/statistics.asp> (visited Apr. 8, 2002). Revenues of the biotechnology industry grew from \$8 billion in 1993 to \$22 billion in 2000.

¹²Hensley & Lueck, *supra* note 2. For example, Celera Genomics, the company which established its reputation by competing

Biotechnology's commercial potential has been recognized not only in the United States, but also around the world. A striking illustration of the high expectations for the industry is that several Asian countries have identified biotechnology as a pillar of their economic development strategies. For example, Singapore is investing in biomedicine to bring the country out of its worst-ever recession. Its \$15 billion plan to transform undeveloped areas of the country into a center for research and development in the life sciences and information technology includes a research park called the Biopolis, a communication network called the Biomedical IT grid, and a "human tissue bank" called the Singapore Tissue Network.¹³ Underscoring Singapore's "total commitment to developing its biomedical-sciences industry,"¹⁴ Singapore has also begun wooing scientists and companies from other countries with a favorable regulatory environment and a \$500 million venture capital fund. Recently, Singapore celebrated the decision by Alan Colman, a researcher from the company that cloned Dolly the sheep, to move to Singapore.¹⁵

Other Asian countries are betting on biotechnology as well. China has established a national fund to support domestic research and import foreign scientists with expertise: "[S]ome in Beijing hope the biotech revolution will provide China with what Sputnik gave the Soviet Union: an entrée into the ranks of scientifically advanced nations – but with an even bigger commercial payout. For now, its rapid gains in the field are likely at least to give it a prominent voice in shaping global biotech policies."¹⁶ Taiwan has also announced plans to boost its biotechnology sector as part of an economic strategy to focus on higher value industries, such as biotechnology and information technology, rather than lower and middle value industries which have become increasingly competitive.¹⁷ According to its Biotech Industry Development Master Plan, Taiwan

with the NIH to map the human genome, is under pressure to show that it has a long-term business plan beyond its ability to quickly sequence human and animal genomes.

¹³Tan Ooi Boon, *Singapore Seeks Biomedical Tie-ups with European Players*, SINGAPORE STRAITS TIMES, Mar. 2, 2002, available in 2002 WL 4328156.

¹⁴*Id.* Statement by Philip Yeo, chairman of Singapore's Agency for Science Technology and Research and co-chairman of the Economic Development Board.

¹⁵Alexa Olesen, *Sheep Cloning Scientist to Move*, AP ONLINE, Mar. 6, 2002, available in 2002 WL 16386858.

¹⁶Karby Leggett and Antonio Regalado, *Fertile Ground: As West Mulls Ethics, China Forges Ahead in Stem Cell Research*, WALL ST. J., Mar. 6, 2002, at A1, available in 2002 WL-WSJ 3387799.

¹⁷*Genetic Variations Next Trend in Bioindustry*, CHINA POST, Mar. 2, 2002, available in 2002 WL 5755835.

will invest \$500 million over the next five years, aiming to create 500 biotechnology companies over the next 10 years and grow industry revenue by 25% each year. Korea has also announced its intention to establish an institute to support the biotechnology industry as well as a fund to invest in biotechnology companies.¹⁸ Beyond the therapeutic and commercial benefits it will yield, biotechnology will have a significant impact on society itself. As Nobel Laureate and Cal Tech president David Baltimore predicts, “Biology will become an engine of transformation of our society. Instead of guessing about how we differ from one from another, we will understand and be able to tailor our life experiences to our inheritance. We will also be able, to some extent, to control that inheritance.”¹⁹ Biomedical progress therefore prompts profound questions about whether science’s potential social implications warrant restrictions on scientific manipulation. As one author suggests, “cloning is perhaps the most ethically, morally and legally consequential scientific discovery of mankind since the invention of nuclear weapons.”²⁰

Like many other technological advances, biotechnology is a double-edged sword. It can be applied for unquestionably beneficial purposes as well as unequivocally harmful ones, with many potential applications falling into a “gray zone” between these extremes. As described by

political and social theorist Francis Fukuyama:

Biotechnology falls somewhere between... technologies which absolutely require regulation, such as nuclear technology, and technologies which are relatively benign, such as the personal computer. Transgenic crops and human genetic engineering make people far more uneasy than do personal computers or the Internet. But biotechnology also promises important benefits for human health and well-being. When presented with an advance like the ability to cure cystic fibrosis or diabetes, it is hard for people to articulate reasons why their unease with the technology should stand in the way of progress.²¹

¹⁸ *Korean Government to Strengthen Support for Biotech Industry*, ASIA PULSE, June 27, 2000, available in 2000 WL 20935966.

¹⁹ Ralph Brave, *Governing the Genome: Which Genetic Modifications Should Be Encouraged and Which Outlawed? Deep Divisions Exist Even Among Ethical Scientists and Informed Activists*, THE NATION, Vol. 273, Issue 19, Dec. 10, 2001, available in 2001 WL 2133084.

²⁰ Paul Tully, *Dollywood Is Not Just a Theme Park in Tennessee Anymore: Unwarranted Prohibitory Human Cloning Legislation and Policy Guidelines for a Regulatory Approach to Cloning*, 31 J. MARSHALL L. REV. 1385, 1386 (1998).

Not surprisingly, concerns about biotechnology have begun to assume a higher profile in public discourse. Stories about the human genome, cloning, and stem cells have graced newsmagazine covers, paraded in newspaper headlines, and dominated television talk show debates. Congress has considered legislation on a variety of biotechnology-related topics, from genetic privacy to transgenic crops. President Bush's nationally televised, prime time address devoted to stem cell policy reflects a priority on biotechnology issues which may be a harbinger of the future. As Arthur Caplan, a noted bioethicist and director of the Center for Bioethics at the University of Pennsylvania, commented, "Bioethics probably has topped the chart of its visibility when the president makes his first speech on bioethics and appoints his bioethics advisor. I guess that's bigger than I would have guessed we would get."²²

Determining whether and how to regulate biotechnology will be extremely difficult, however. Many of the questions that biotechnology raises are ones on which reasonable people can, and do, differ. As Caplan asks, "That map over there [of the human genome] is going to generate more stuff. Are we going to test people's genes in the workplace? Are we going to engineer people to be stronger, faster, better? Are we going to try and tweak those genes to live forever?"²³ The answers to these questions hinge on deeply held moral, religious, and socially-constructed values which people hold in a wide – and often irreconcilably arrayed – range of permutations. As one author notes, "We live, after all, in a pluralistic society where uniformity of opinion is virtually impossible."²⁴

Given the difficulty of resolving these value-laden debates, there is a tendency to defer to the rationality

²²Bill Bergstrom, *Bioethicists Address 'Deep Questions' Debate: Such Complex Issues as Cloning, Genome Mapping and Stem Cell Research Have Pushed the Formerly Obscure Field into Prominence*, L.A. TIMES, Sept. 30, 2001, at A27, available in 2001 WL 2521991.

²³*Id.*

²⁴Charity Scott, *Why Law Pervades Medicine: An Essay on Ethics in Health Care*, 14 NOTRE DAME J.L. ETHICS & PUB. POL'Y 245, 258 (2000).

of science. During the 2001 Congressional cloning debate, Representative Strickland (D-OH) argued that policy should be guided by the best available science and that “we should not allow theology, philosophy, or politics to interfere with the decision we make on this issue.”²⁵ Fukuyama notes the post-Enlightenment phenomenon that the public often tends to trust scientists more than politicians:

Efforts by politicians to limit what scientists do in their own domain evoke memories of the medieval Catholic Church branding Galileo a heretic for saying the earth revolves around the sun. Since the time of Francis Bacon, the pursuit of scientific research has been seen to carry its own legitimacy as an activity that serves the broader interests of mankind.²⁶

Bioethical dilemmas are further complicated by an immense degree of uncertainty about the future of scientific discovery. It is impossible to predict how extensive or limited the potential for genetic alteration will be. On one hand, nature may foil scientists’ best efforts to control the genome, thereby obviating some of the most vexing fears about biotechnology. For example, if the genes for traits such as intelligence and athletic prowess prove to be too complicated for scientists to pinpoint, the prospect that parents will demand “designer babies” will never materialize. On the other hand, there may be no limits to biomedical progress, with the only real question being how quickly this progress will unfold. In this case, the bioethical questions which society is currently facing will be only the beginning of more extensive discussions that may even have to contemplate “the end of the human species as such.”²⁷ Perhaps Francis Fukuyama’s eerie conception of a “post-human future” is not an impossible one:

²⁵Fukuyama, *supra* note 21.

²⁷*Id.*

Ultimately, the technologies developed by these companies, as well as by researchers in government and academia, may lead us into a post-human future in which we have the capacity, slowly but surely, to alter the essence of human nature. Many embrace this power under the banner of human freedom... the freedom of parents to choose the kind of children they have, the freedom of scientists to pursue research, and the freedom of entrepreneurs to make use of the new technologies to create wealth. But this kind of freedom will be different from all other freedoms that people have previously enjoyed... we will deliberately take charge of our own biological makeup rather than leaving it to the blind forces of natural selection... Many assume that the post-human world will look pretty much like our own – free, equal, prosperous, caring, compassionate – only with better health care, longer lives, and perhaps higher levels of intelligence than today.

But the post-human world could be one that is far more hierarchical and competitive than the one that currently exists, and full of social conflict as a result. It could be one in which any notion of shared humanity is lost, because we have mixed human genes with those of so many other species that we no longer have a clear idea of what a human being is. It could be one in which the average person is living well into his or her second century, sitting in a nursing home hoping for an unattainable death. Or it could be the kind of soft tyranny envisioned in *Brave New World*, in which everyone is healthy and happy but has forgotten the meaning of hope, fear, or struggle.”²⁸

Fortunately, it is widely accepted that consideration of bioethical issues is crucial; however, the current condition of bioethics policy in the United States is deeply unsatisfactory. There are few clear bioethical guidelines or regulations, and even where regulations have been issued, their effectiveness is dubious. As one author describes:

[T]he state of human cloning regulation in the United States is one of uncertainty, and even confusion. Moratoria were declared, but they did not have a discernible policy effect. State laws have been passed, but offer limited assurance against human cloning. The private sector, left free of regulation, has been asked to voluntarily comply. The FDA has asserted jurisdiction, although the agency may not have the authority or the resources to deal with the controversial issue.²⁹

Undoubtedly, one major reason that clearer standards have not been established is that it is extremely challenging to reach consensus on these issues. While many valuable discussions have taken place, they have been waged within separate silos, e.g., biotechnology companies, religious institutions, universities, think tanks, non-governmental organizations. Stark differences in interests, perspectives, and vocabularies make it difficult for these silos to talk to each other. As one author notes:

... I would like to call attention to one feature of that discussion, a feature that will make it very difficult for our legislatures and for our courts to arrive at a cloning policy that will be acceptable to more than a handful or two of the participants in that discussion. The feature that I have in mind is the deep diversity that exists among the discussants, a diversity so deep that on several points it will not only be difficult for them to reach agreement; it will also be difficult for them to understand each other at all.³⁰

Another problem with bioethical discussion in the United States is that it has not been as transparent to the general public as would be desirable. Although deliberative bodies such as the National Bioethics Advisory Commission (NBAC) held extensive public hearings and solicited comments from all interested parties, the public must have more than just the opportunity to participate in these discussions. It must also have sufficient information to participate meaningfully in them. Unfortunately, one writer's description of the current situation may be accurate:

Deliberative democracy, viewed as but a complement to the legislative process, is an attractive idea. The principal drawback to its effective implementation is that the average, ordinary, reasonable American is not sufficiently informed to enter into meaningful discourse on the ramifications of the new Age of Biotechnology. Logic is too often put on "hold" while emotional feelings control and often resolve the debate.³¹

The unsatisfactory state of bioethics today threatens to become increasingly problematic as scientific advances raise more and more bioethical dilemmas. Somehow, the current policy deadlock must be broken. Because bioethical issues are so controversial and perhaps even objectively indeterminate,³² it may be necessary, as a first matter, to determine what kind of process could facilitate the adequate resolution of bioethical dilemmas. The "how" of bioethics policy must be established before it is possible to discuss what the correct – or at least the most plausible³³ – bioethical policies may be. A policy development process which systematically encourages and incorporates a wide range of perspectives is more likely to reach the "right answers" – i.e., policies which endure over time, satisfy the broadest range of groups in a heterogeneous society, and

³²*Id.* at 98. "An overriding concern of any study of applied bioethics over the years to come is the extent to which diverse notions about ethics and bioethics will be reconciled."

³³Scott, *supra* note 24, at 258: "What is meant by 'consensus' is less than unanimity and more a sense of general agreement. Whether a bare majority or a substantial majority, 'consensus'... means a democratic resolution we have agreed to abide by in our social contract, even if individually some (or even many) of us believe a particular resolution is wrong."

are respected and followed by those who must abide by them. In contrast, an imperfect process is likely to yield policies which are divisive and which may be slowly but steadily undermined by those who disagree with them or the way they were derived.

The American democratic process has proven to be a suitable forum for debating and deciding difficult issues with significant societal implications; however, the democratic process sometimes needs assistance to function properly, and knotty bioethical issues present one such context. This paper therefore considers the type of process which could facilitate the resolution of bioethical dilemmas. This discussion has been divided into four sections:

I.

II.

III.

IV.

Section I: Overview of Efforts to Craft Bioethical Standards and Policies

There has been no dearth of bioethical discussion in the United States. In fact, there has been a tremendous amount of debate, and a multitude of parties – from the private sector to the federal government, from think tanks to universities – have undertaken efforts to articulate bioethical standards and policies. As the following overview indicates, however, few widely accepted principles have emerged, and only a handful of regulations have been placed in force.

The private sector

In recognition of the ethical implications of their work, biotechnology and pharmaceutical companies have begun to establish relationships with bioethicists. Caplan even asserts that bioethicists have become as essential to biotechnology companies as more traditional advisers such as lawyers and accountants.³⁴ While it is heartening that private companies have taken the initiative to conduct business in a bioethically responsible way, a skeptic could reasonably question whether bioethicists can provide meaningful guidance to companies which pay them for their advice.³⁵

Indeed, the relationships between companies and “bioethicists-on-retainer” have raised many eyebrows. Pharmaceutical and biotechnology companies have established many types of arrangements with bioethicists, ranging from consulting agreements with individual bioethicists and appointments to advisory boards,³⁶ to in-house bioethics panels and bioethics centers at universities.³⁷ Since private sector companies offer large

³⁴Bruce Sylvester, *In-house Ethics Czars Seen as Vital in Age of Stem Cells, Cloning*, BIOTECHNOLOGY NEWSWATCH, Oct. 1, 2001, available in 2001 WL 8787967.

³⁵Sheryl Gay Stolberg, *Bioethicists Fall Under Familiar Scrutiny*, N.Y. TIMES.COM, Aug. 1, 2001.

³⁶Carl Elliott, *Pharma Buys a Conscience*, AMERICAN PROSPECT, Vol. 12, Issue 17, Sept. 24, 2001, available in 2001 WL 7681208. The advisory boards of major biotechnology and pharmaceutical companies are littered with the names of leading bioethicists, e.g., Nancy Dubler of Montefiore Medical (DNA Sciences); Ronald Green of Dartmouth University (Advanced Cell Technology); Arthur Caplan of the University of Pennsylvania (Celera Genomics, DuPont); Karen Lebacqz of the Pacific School of Religion (Geron Corporation); Evan DeRenzo (Janssen Pharmaceuticals).

³⁷*Id.* Industry-university relationships include SmithKline Beecham’s sponsorship of the genetics program at the Stanford University Center for Biomedical Ethics; Merck Company Foundation’s financing of several international ethics centers (e.g., in Ankara, Turkey and Pretoria, South Africa); Aventis Pharmaceuticals Foundation’s funding of the Research Integrity Project

sums of money to bioethicists and their affiliated institutions, there are concerns that bioethicists' judgments may be influenced by financial considerations. The bioethics community has not established any guidelines for appropriate financial arrangements with private sector companies, so companies currently have wide latitude to exercise their financial clout to find friendly and amenable bioethicists. As described by the eminent ethicist and philosopher Dr. Daniel Callahan, "This is a semiscandalous situation for my field. These companies are smart enough to know that there are a variety of views on these subjects, and with a little bit of asking or shopping around you can find a group that will be congenial to what you are doing."³⁸

A recent incident shows how companies may condition their financial support on favorable opinions. In 2000, the Hastings Center, an institute for bioethics research and education,³⁹ lost an annual \$25,000 grant from the pharmaceutical company Eli Lilly after the Center published an article by a writer who was critical of Lilly's blockbuster anti-depressant drug, Prozac. Although Lilly denies that the article's publication was the reason for the withdrawal of the grant, the sequence of events is suspicious, especially since the writer's appointment at the University of Toronto's Center for Addiction and Mental Health, which also received a gift from Eli Lilly, was rescinded after he gave a talk which raised concerns about Prozac.⁴⁰ As one writer describes, corporations can exert influence over the bioethicists they sponsor, even without outright pressure: "Corporate money is so crucial to the way that university medical centers are funded today that no threats or offers need actually be made in order for a company to exert its influence. The mere presence of corporate money is enough."⁴¹

The situation is exacerbated by the lack of credentialing standards for bioethicists. As R. Alta Charo, a

at the Midwest Bioethics Center.

³⁸Stolberg, *supra* note 35.

³⁹The salience of bioethics issues has prompted the formation of many think tanks like The Hastings Center. The Hastings Center is a well established and highly regarded think tank devoted to the interdisciplinary study of bioethical issues. Founded in 1969 in Garrison, New York, it was the first institute devoted to the study of ethical issues in medicine and has considered a wide range of questions, from the right to die and distribution of scarce organ transplants, to informed consent and surrogate parenting. See The Hastings Center website <www.thehastingscenter.org> (visited Apr. 8, 2002).

⁴⁰Elliott, *supra* note 36.

⁴¹*Id.*

professor of law and medical ethics at the University of Wisconsin, commented, “Anybody can stand up and claim to be an ethicist; there is no licensing, there is no accreditation.”⁴² Reflecting the multidisciplinary nature of the discipline, the current ranks of bioethicists comprise many types of professionals, including doctors, nurses, theologians, lawyers, and anthropologists. Not all bioethicists have had medical or scientific training, but most have had experience on hospital ethics panels or university research review boards. As a growing number of universities establish bioethics graduate programs, the corps of bioethicists will begin to include more people with specific academic training in the field. The heterogeneity of bioethicists’ backgrounds is not necessarily problematic; in fact, it is probably fortunate. At the same time, one can legitimately wonder whether the self-appointed bioethicists who are called on to make important value judgments are sufficiently qualified to do so. In the strong words of one critic, “The bioethicists have set themselves up, almost like Napoleon crowning himself emperor, as the arbiters of what is moral and ethical in health care... [and even a] hairdresser has to have a license.”⁴³

Furthermore, bioethicists seem to have little to no accountability for their decisions. For example, when the Jones Institute for Reproductive Medicine drew broad criticism for its experiments with human embryos, the Institute retorted that its protocols had been cleared by three separate ethics panels. The Institute refused to name its ethicists, however, claiming that “[w]hen people signed on to participate in the ethics review, that was not with the understanding that their names would be made public. That wasn’t part of the deal.”⁴⁴ Where open disclosure should be the norm, it is disconcerting that bioethicists could ask for and receive protection of their identities.

Taken together, all of these factors – the financial leverage that private companies have over bioethicists

⁴²Stolberg, *supra* note 35.

⁴³*Id.*, quoting Wesley J. Smith, author of *CULTURE OF DEATH: THE ASSAULT ON MEDICAL ETHICS IN AMERICA* (Encounter Books, 2000).

⁴⁴*Id.*

and their institutions, the lack of minimum qualifications for bioethicists, and the dearth of accountability – have fueled charges that bioethicists are being used as fig leaves for controversial projects. According to one theologian, “Bioethicists don’t realize it, but they are the pawns in this whole debate.”⁴⁵ Similarly, Carl Elliott, a bioethicist at the University of Minnesota, warns:

Bioethics boards look like watchdogs, but they are used like show dogs. What better way for a corporation to polish its image than to parade an ethics consultant before its critics? What better way to head off litigation than to run its plans by an in-house ethics board? No matter how outrageous a corporate policy, no matter how troubling a headline in the morning paper, it will be softened by the knowledge that the corporation in question has consulted with a team of ethics experts. Better to buy a bioethicist now than to be attacked by one later. The only challenge is how to disguise the job so that bioethicists do not realize they have been bought?⁴⁶

Because bioethics is an inherently subjective inquiry, it is difficult to prove whether bioethicists are in fact influenced by the companies which pay them. The diversity of moral, political, and intellectual perspectives generates a large universe of potentially “correct” opinions. Since it is impossible to “audit” bioethicists for objectivity, the financial relationships between bioethicists and private industry inevitably raise questions about the credibility of these bioethicists’ decisions. As Elliott describes:

The point is that certain people in whom public trust is placed... must be financially disinterested. What is more, they must be seen as disinterested; otherwise, the institution they represent risks falling apart... Part of the problem is aesthetic. It is unseemly for ethicists to share in the profits of [companies which may engage in unethical practices.] But credibility also is an issue. How can bioethicists continue to be taken seriously if they are on the payroll of the very corporations whose practices they are expected to assess?⁴⁷

In light of these perceived – or actual – conflicts of interest, it is unlikely that private companies’ consultations with bioethicists can be a reliable source of compelling bioethical guidelines.

Federal government – Executive Branch

⁴⁵ *Id.*, quoting Nigel M. de S. Cameron.

Several efforts to study and address bioethical issues have been undertaken by the President and Executive agencies, and these efforts have made valuable contributions to the deeper understanding of these issues. For example, the dozens of public hearings held by the National Bioethics Advisory Council (NBAC) yielded a rich corpus of background information⁴⁸ which will serve as a resource for future bioethical debates. Few concrete, lasting bioethics policies have emerged from these Executive Branch initiatives, however. Many of these initiatives were designed to be primarily deliberative, with no enactment or enforcement powers conferred to the institutions they established. Also, many of these initiatives were created for a limited period of time to address a specific set of issues. As the following overview shows, the Executive Branch can play an important role in bioethical discussion; however, it may not be the ideal place to plant principal responsibility for making policy.

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Although previous administrations addressed bioethical issues,⁴⁹ it is appropriate to begin a survey of Presidential initiatives during the genetics era with the National Bioethics Advisory Council (NBAC). President Clinton established the NBAC by Executive Order⁵⁰ in October 1995 to serve as an advisory body to the National Science and Technology Council, a group of Cabinet-level officials chaired by President Clinton. The NBAC was composed of 17 members appointed by President Clinton,⁵¹ and it was established for a

⁴⁸A compilation of NBAC documents is available at <<http://bioethics.georgetown.edu/nbac/pubs.html>> (visited Apr. 8, 2002). The topics that NBAC considered included human cloning, research involving persons with mental disorders, research with human biological materials, stem cell research, and clinical trials in developing countries.

⁴⁹E.g., at President Carter's request, Congress established the Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research in 1978. In 1982, the Commission disbanded after issuing reports on 10 pressing issues: the definition of death, informed consent, genetic screening and counseling, disparities in the availability of health care, life-sustaining treatment, privacy and confidentiality, genetic engineering, compensation for injured subjects, whistleblowing in research, and the IRB guidebook.

⁵⁰Exec. Order No. 12,975, 60 Fed. Reg. 193 (1995).

⁵¹The members were Dr. Harold Shapiro, President of Princeton University; Dr. Patricia Backlar, Research Professor of Bioethics at Portland State University and Assistant Director of the Center for Ethics in Health Care at Oregon Health Sciences University; Dr. Arturo Brito, Assistant Professor of Clinical Pediatrics at University of Miami; Alexander Capron, Professor of Law and Co-Director of the Pacific Center for Health Policy and Ethics at University of Southern California Law

period of two years, although it was reauthorized several times. NBAC's mandate was to identify broad ethical principles, rather than to review and approve specific projects.⁵² Substantively, NBAC's priority was to consider how to safeguard the rights and welfare of human research subjects, since the primary impetus for establishing NBAC had been concerns that volunteers in clinical studies were not receiving sufficient information about the risks of participating in research trials.⁵³ Only as a second priority was NBAC expected to tackle other bioethical questions.⁵⁴

This second priority assumed a much higher profile, however, when Scottish scientists announced in February 1997 that they had successfully cloned a sheep named Dolly. The cloning of Dolly through a procedure called nuclear transfer⁵⁵ represented a significant scientific step beyond cloning techniques which were available at that time, and the procedure raised the realistic possibility that human cloning could be feasible in the future. In response, President Clinton announced a moratorium on the use of federal funds for human cloning research and directed the NBAC to consider the implications of human cloning research and make appropriate recommendations within 90 days. In its report, the NBAC concluded that the early stages of cloning technology made human research too risky and that moral qualms outweighed cloning's practical

Center; Dr. Eric Cassell, Professor of Public Health at Cornell Medical College; R. Alta Charo, Professor of Law and Medical Ethics at University of Wisconsin; Dr. James Childress, Professor of Religious Studies and Medical Education at University of Virginia and Co-Director of Virginia Health Policy Center; Dr. David Cox, Scientific Director of Perlegen Sciences; Dr. Rhetaugh Dumas, Vice Provost Emerita and Dean Emerita and Professor of Nursing at University of Michigan; Dr. Carol Greider, Professor of Molecular Biology and Genetics at Johns Hopkins University; Steven Holtzman, Chief Business Officer of Millennium Pharmaceuticals; Bette Kramer, Founding President of Richmond Bioethics Consortium; Dr. Bernard Lo, Director of Program in Medical Ethics at University of California in San Francisco; Dr. Lawrence H. Miike, M.D., J.D.; Dr. Thomas Murray, President of the Hastings Center; William Oldaker, Senior Partner, Oldaker and Harris, LLP and Co-Founder and General Counsel, NeuralStem Biopharmaceuticals; Dr. Diane Scott-Jones, Professor of Psychology at Boston College.

⁵²Exec. Order No. 12,975, *supra* note 50, §§ 4(b) and 4(c).

⁵³Exec. Order No. 12,975, *supra* note 50, § 5(a), reads as follows: "As a first priority, NBAC shall direct its attention to consideration of: protection of the rights and welfare of human research subjects; and issues in the management and use of genetic information, including but not limited to, human gene patenting."

⁵⁴Exec. Order No. 12,975, *supra* note 50, § 5(b) provides that NBAC should consider four criteria in establishing its priorities other than those enumerated in § 5(a): the public health or public policy urgency of the bioethical issue; the relation of the bioethical issue to the goals of federal investments in science and technology; absence of another entity capable of considering the issue appropriately; the extent of interest in the issue within the federal government. § 4(d) further provides that NBAC can accept suggestions for topics to consider not only from the National Science and Technology Council, but also from Congress and the public. NBAC itself can also identify issues that it would like to examine, subject to approval by the National Science and Technology Council.

⁵⁵In nuclear transfer cloning, the nucleus of a female egg cell is removed and replaced by the nucleus of a somatic cell. The DNA from the somatic cell becomes the genetic basis of the organism which develops from the egg cell and is therefore an asexually-produced, identical genetic copy of the somatic cell donor.

value at that time. NBAC recommended that the moratorium on federally funded human cloning research be maintained and urged Congress to pass legislation to prohibit cloning, but with a sunset provision which would allow Congress to revisit cloning policy in the future.⁵⁶ President Clinton submitted legislation to Congress based on these recommendations, but Congress failed to enact it.

Following the 1998 announcement that University of Wisconsin researchers had isolated human embryonic stem cells, NBAC also considered the ethics of stem cell research. After extensive study, it issued a report in 1999⁵⁷ which concluded that federal funding for stem cell research should be limited to research involving specific types of stem cells. It outlined a monitoring mechanism, including a National Stem Cell Oversight and Review Panel, to ensure that these restrictions would be heeded, and it urged the private sector to voluntarily comply with these restrictions as well. These recommendations were influential in the NIH's development of guidelines for federal funding of embryonic stem cell research.⁵⁸

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According to the terms of the Executive Order that created it, NBAC expired in October 2001. Having highlighted his opposition to the Clinton administration's stem cell policy during the 2000 election campaign, President Bush announced upon assuming office that his administration would revisit the NIH guidelines for federally funded stem cell research. Ultimately, the guidelines were revised to allow the continuing use of

⁵⁶NBAC was also explicit about urging that the ban be phrased carefully to allow other valuable areas of scientific research, including cell line cloning, to continue.

⁵⁷*Ethical Issues in Human Stem Cell Research* (National Bioethics Advisory Commission, Rockville, MD), Sept. 1999, available in <<http://bioethics.georgetown.edu/nbac>> (visited Apr. 8, 2002).

⁵⁸These guidelines permitted federal funds to be used for human embryonic stem cell research, but only with discarded human embryos. The intentional creation of embryos for such research was forbidden.

federal funds for stem cell research, but only with stem cells which had been created before August 2000.⁵⁹ Along with this announcement of the new stem cell policy, President Bush indicated that he would appoint a Council on Bioethics (“Council”).⁶⁰ The Council’s mandate is very broad. Although specific issues, such as embryonic stem cell research, assisted reproduction, and cloning, are mentioned in its charter, the Council is also empowered to study broader issues not tied to specific technologies, such as the appropriate uses of biomedical technologies and the consequences of limiting scientific research.⁶¹ Like NBAC, the Council is expected to consider bioethical issues in general terms; it is not empowered to review specific projects or develop regulations.⁶² The charter further indicates that the Council should not feel pressured to achieve consensus. Rather, it should be “guided by the need to articulate fully the complex and often competing moral positions on any given issue... The Council may therefore choose to proceed by offering a variety of views on a particular issue, rather than attempt to reach a single consensus position.”⁶³

The 17 members of the Council were appointed by President Bush and include prominent academics from a wide range of disciplines and one journalist.⁶⁴ The Council assembled for the first time in January 2002 and began its deliberations with issues related to human cloning. In particular, it has been charged with

⁵⁹It is believed that over 60 of these cell lines are available at 11 different academic and private laboratories in the United States and around the world; however, it is still unclear how many viable stem cell lines will actually be available to researchers because the cell lines have not yet been fully characterized.

⁶⁰Exec. Order No. 13,237 (Nov. 28, 2001). Like NBAC, the Council will terminate within 2 years unless extended by the President prior to its expiration. § 5(b).

⁶¹Exec. Order No. 13,237, *supra* note 60, § 2(b).

⁶²Exec. Order No. 13,237, *supra* note 60, § 2(d).

⁶³Exec. Order No. 13,237, *supra* note 60, § 2(c).

⁶⁴Sheryl Gay Stolberg, *Bush’s Advisers on Ethics Discuss Human Cloning*, N.Y. TIMES.COM, Jan. 18, 2002. Members include Dr. Leon Kass (chairman), professor of bioethics at University of Chicago; Dr. Elizabeth Blackburn, professor of biochemistry and biophysics at University of California at San Francisco; Dr. Stephen Carter, law professor at Yale University; Dr. Rebecca Dresser, law professor at Washington University; Dr. Daniel Foster, chairman of internal medicine at University of Texas Southwestern Medical School; Dr. Francis Fukuyama, professor of international political economy at Johns Hopkins University; Dr. Michael Gazzaniga, director of Center for Cognitive Neuroscience at Dartmouth College; Dr. Robert P. George, professor of jurisprudence at Princeton University; Dr. Alfonso Gomez-Lobo, professor of metaphysics and moral philosophy at Georgetown University; Dr. Mary Ann Glendon, law professor at Harvard University; Dr. William Hurlbut, professor of human biology at Stanford University; Mr. Charles Krauthammer, columnist for the Washington Post; Dr. William F. May, emeritus professor of ethics at Southern Methodist University; Dr. Paul McHugh, director of the department of psychiatry and behavioral sciences at Johns Hopkins University; Dr. Gilbert Meilaender, professor of Christian ethics at Valparaiso University; Dr. Janet Rowley, professor of medicine, molecular genetics and cell biology, and human genetics at the University of Chicago; Dr. Michael Sandel, professor of government at Harvard University; Dr. James Q. Wilson, emeritus professor of management and public policy at University of California at Los Angeles.

considering two questions: whether cloning should be used to produce babies which are genetically identical replicas of a parent (“reproductive cloning”) and whether scientists should clone embryos to obtain cells for the treatment of disease (“therapeutic cloning”).

Given its recent formation, the Council has not yet issued any findings or reports, and it has not indicated when it expects to do so. Although judgment must be reserved until the Council has had a chance to act, many critics have expressed concerns that the Council is insufficiently inclusive and ideologically slanted. Patient advocates have noted that the Council lacks any representatives of the chronically ill, who could significantly benefit from cloning technology. Other critics have pointed out that 14 of the 17 members are men and that most members are white.⁶⁵ The chairman of the Council and President Bush’s personal bioethics adviser, Dr. Leon Kass, is well-known for his strong opposition to cloning;⁶⁶ moreover, President Bush’s remarks to the Council at its first meeting seem to presume a conservative bias. Exhorting the Council to “be the conscience of the country,” he indicated that he viewed the role of the Council as helping people “come to grips with how medicine and science interface... [with]... the dignity of life, and the notion that life is – you know, that there is a Creator.”⁶⁷ Most recently, President Bush evinced his position even more explicitly by inviting opponents of cloning research to the White House to rally support for pending legislation in the Senate which would ban both reproductive and therapeutic cloning.⁶⁸

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The Recombinant DNA Advisory Committee (RAC) was established in October 1974 by the Department of Health, Education & Welfare⁶⁹ in response to the advent of DNA splicing technology. This technology,

⁶⁵*Id.*

⁶⁶*Id.*

⁶⁷*Id.*

⁶⁸Sheryl Gay Stolberg, *Bush Rallies Opponents of Cloning*, N.Y. TIMES.COM, Apr. 10, 2002.

⁶⁹This Department is now known as the Department of Health and Human Services (HHS).

which enables gene transfer, emerged in 1973 when Stanford scientists successfully inserted DNA from a simian cancer virus into *E. coli*, a bacteria which lives in human intestines. Fellow scientists were concerned about the technique and called for the suspension of further experimentation until safety could be assured. In February 1975, the National Academy of Sciences convened a group of scientists, lawyers, and journalists to consider the implications of and proper response to gene splicing technology. Although a primary purpose of the conference was to alleviate widespread fears about the technology, the Conference ended up being a public relations disaster. Even the journalists who attended the Conference walked away worrying whether scientists would create a lethal “Andromeda Strain.”

Amid intense public pressure, the RAC drew up strict regulations for gene transfer experiments. All gene transfer protocols were required to obtain RAC approval, and the RAC subjected these protocols to exhaustive review. For example, the RAC drafted a set of over 100 questions which addressed the scientific merits, ethical propriety, and public safety consequences of gene therapy research. Researchers had to answer these questions in hearings which were open to the public, and institutions conducting RAC-approved, federally funded research were required to establish an Institutional Biohazard Committee (IBC) to supervise genetic research locally and ensure compliance with RAC regulations.⁷⁰

Over time, public alarm about gene transfer technology subsided. By the 1980s, patient advocates even began to criticize the RAC review process as too slow and argued that it was hampering the development of therapies for AIDS, cancer, and other deadly diseases.⁷¹ The RAC met only 3 times per year and thus could not quickly address the growing number of protocols coming before it. Bowing to pressure, the RAC assessed its regulatory role and crafted a revised process that decreased its role. The RAC ceded routine oversight of gene transfer experiments to the FDA, while retaining the authority to conduct more detailed review of protocols which used novel methods or raised new policy issues. As the FDA assumed more responsibility for

⁷⁰Joseph M. Rainsbury, *Biotechnology on the RAC – FDA/NIH Regulation of Human Gene Therapy*. 55 FOOD & DRUG L.J. 575, 581 (2000).

⁷¹*Id.* at 583.

gene therapy regulation, the nature of the regulatory oversight changed; namely, it became less normative and more technical. Whereas the RAC had raised many ethical and public safety questions, the FDA focused on matters such as pre-clinical safety data and long-term monitoring of the health of research participants.⁷² Eventually, the RAC's role had diminished so much that NIH Director Harold Varmus proposed to shrink the RAC. Its membership was decreased from 25 to 15, and its authority over novel gene therapy protocols was essentially dismantled. Although researchers must still respond to RAC questions, the RAC no longer has any decisive power; it can only advise the FDA. In essence, the RAC has become a deliberative body, or as one commentator ruefully described, "a debating society" for controversial gene therapy protocols. At a workshop conducted on the 25th anniversary of the establishment of the RAC, scientists and regulators concluded that the RAC could no longer effectively oversee the biotechnology industry.⁷³

Although the RAC has little impact today, many acknowledge that it played a key role in the appropriate introduction and current acceptance of gene therapy:

Despite recent controversy, federal oversight of the commencement of human gene therapy clinical trials represents a regulatory success story. In a culture frequently mistrustful of biotechnology advances, gene therapy has provided an open forum for intelligent deliberation about the risks and benefits of gene therapy. A key component to this success has been the RAC. Although not immune to political pressure, RAC review of the first human gene therapy protocols has been measured, informed, and most importantly, transparent...⁷⁴

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⁷²The RAC had already been weakened by HHS in 1981, when the IBCs, which had been established to ensure the implementation of RAC regulations, were consolidated with and subordinated to the Institutional Review Boards (IRBs), which had been mandated in 1974 by the National Research Act. The National Research Act was passed in response to revelations of severe abuses of participants in clinical trials, e.g., the Jewish Chronic Disease Hospital scandal, where chronically ill and weak patients were injected with live cancer cells; the Willowbrook scandal, where mentally retarded children were infected with hepatitis; and the Tuskegee syphilis scandal, where 400 black men diagnosed with syphilis were put under observation but not informed of their condition. The Act required the implementation of IRBs to oversee clinical trials at all institutions conducting federally funded research.

⁷³Fukuyama, *supra* note 21.

As detailed above, the FDA inherited responsibility for gene therapy from the RAC, and in January 1998, the FDA asserted jurisdiction over human cloning research.⁷⁵ For the FDA to be capable of regulating cloning research, cloned embryos would have to fall within the scope of the statutes which empower the FDA. More specifically, cloned embryos would have to be considered a drug or device under the Federal Food, Drug, and Cosmetic Act of 1938 (FDCA) or a biological product under the Biologics Act.⁷⁶ Although the FDA's assertion of authority over cloning has not been tested in court, its legality is dubious. As one writer contends, the arguments for FDA jurisdiction appear to be "legally unsupportable"⁷⁷ based on a common sense reading of the statutes, their legislative intent, and their traditional interpretation.⁷⁸

To have jurisdiction over cloning under the FDCA, the FDA must demonstrate that a cloned embryo is a "drug" or "device" as defined by the statute. According to § 201(g) of the FDCA, a "drug" is an "article[] intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and [an] article[] (other than food), intended to affect the structure or any function of the body of man or other animals." A threshold question is whether an embryo is an "article" within the meaning of the statute. Based on the types of items to which this provision has historically been applied, e.g., pharmaceuticals, it is unlikely that a cloned embryo would be considered an "article."⁷⁹

Moreover, even if an embryo were considered an "article," the article must be "intended to treat disease or affect the structure or function of the body." In the context of reproductive cloning, the embryo would be "intended to treat disease" only if the parent or couple were infertile.⁸⁰ If the cloning procedure were an

⁷⁵Elizabeth Price, *Does the FDA Have Authority to Regulate Human Cloning?*, 11 HARV. J.L. & TECH. 619, 624-25 (1998). The Biotechnology Industry Organization (BIO) may have prompted the FDA to claim jurisdiction over cloning because FDA regulation was, from the industry's point of view, a more desirable option than the legislative ban which Congress was considering at the time. The President of BIO sent Donna Shalala, the Secretary of the Department of Health & Human Services, a letter which suggested that the FDA could regulate cloning. Four days later, the Acting Commissioner of the FDA, Michael Friedman, announced that the FDA would assert jurisdiction.

⁷⁶§ 351 of the Public Health Service Act (PHSA).

⁷⁷Price, *supra* note 75, at 641.

⁷⁸Gregory J. Rokosz, *Human Cloning: Is the Reach of FDA Authority Too Far a Stretch?*, 30 SETON HALL L. REV. 464, 501 (2000).

⁷⁹See, e.g., Price, *supra* note 75, at 633; Rokocz, *supra* note 78, at 503-504. These authors point out that legislative intent and a common sense reading of the statute are additional reasons to believe that an embryo is not an "article."

⁸⁰Rokocz, *supra* note 78, at 501.

elective one – i.e., the parent desires a clone merely to create an exact genetic replica of himself or herself – there is no disease which would justify FDA jurisdiction. In the therapeutic cloning context, an embryo could fall within FDA authority since it is intended to produce tissues to treat disease.⁸¹ For both reproductive and therapeutic cloning, one could argue that the implantation of a cloned embryo is “intended to affect the structure or function of the body,” but such a broad reading of the statute is hard to defend. If a cloned embryo is deemed to affect the structure and function of the body, then it would follow that other types of embryos, e.g., embryos produced for *in vitro* fertilization, would fall within the FDA’s jurisdiction. Tellingly, the FDA has never claimed authority over procedures used in infertility clinics.

According to a similar analysis, a cloned embryo is probably not a “device” under the FDCA, where a device is defined in § 201(h) as follows:

[A]n instrument, apparatus, implement... implant... or other similar or related article... which is... intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment or prevention of disease, in man or other animals, or intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes.

Again, a threshold question is whether an embryo is an “instrument, apparatus... or other similar or related article.” The legislative history of the statute clearly suggests that this section was intended to cover items of a mechanical nature, so it is unlikely that an embryo would qualify as a device.⁸² Furthermore, even if one could successfully argue that an embryo is an “article,” one would still have to surmount the hurdle, as in the drug analysis above, of showing that the embryo is “intended to treat disease” or “affect the structure or function of the body.”

⁸¹Price, *supra* note 75, at 630-33.

⁸²*Id.* at 638.

The most plausible basis for FDA jurisdiction may be under the Biologics Act, which empowers the FDA to regulate “biological products.” A “biological product” is defined as a “virus, therapeutic serum, toxin, anti-toxin, vaccine, blood, blood component or derivative... or analogous product, applicable to the prevention, treatment, or cure of diseases or injuries of man.” Since the term “analogous product” is vague, one could conceivably argue that an embryo is one; however, the PHSA was motivated by the desire to assure the safety of vaccines, blood transfusions, and other instruments of public health. It is unlikely that Congress contemplated the regulation of embryos under the Act;⁸³ moreover, one would have to demonstrate that the cloned embryo is intended to treat disease.

The legal basis for FDA jurisdiction therefore appears to be rather tenuous. As one author concludes, “The statutory background, legislative history, and resulting language of the [statutes] clearly demonstrate that Congress neither contemplated the potential ramifications of human cloning procedures nor drafted the statutory language broadly enough to encompass such a radically new technology.”⁸⁴ Furthermore, Congress’ effort to pass cloning legislation suggests that Congress does not intend to delegate regulatory authority over cloning to the FDA.⁸⁵

Even if the FDA were to have valid jurisdiction over cloning under its empowering statutes, it is questionable whether the oversight regime would be desirable. Since jurisdiction hinges on whether the embryo is intended to cure disease, the FDA would be able to regulate therapeutic cloning and reproductive cloning in cases where a parent or couple is infertile. The FDA would have no authority, however, over reproductive cloning for purely elective purposes because there is no disease in this situation. Ironically, then, the FDA would be able to control the more morally palatable uses of cloning technology, but would have no regulatory power over the much more objectionable practice of elective cloning.

Although Congress could amend the empowering statutes to fill such gaps in the FDA’s authority, the FDA

⁸³*Id.* at 639.

⁸⁴Rokocz, *supra* note 78, at 498.

⁸⁵*Id.* at 513.

may still not be a suitable arena for considering the ethical and social implications of human cloning. The agency already has a tremendous number of responsibilities and often lacks sufficient resources to carry them out thoroughly. Also, as illustrated by the transition of gene therapy regulation from the RAC to the FDA, the FDA tends to focus on health and safety, rather than considering more normative questions. As one author states, “Although the FDA appears to be a good candidate for the oversight of genetically manipulated reproductive technology, it may not be the appropriate forum for deciding the moral and ethical limits of the use of such technology.”⁸⁶ It may be impossible, and even unwise, to modify a long-held institutional culture which makes the FDA so effective at its other regulatory responsibilities.

Furthermore, it would be tricky for the FDA to be effective in two very different roles simultaneously. To make bioethics policy, the FDA would have to build consensus among diverse parties, including the same companies and researchers whom the FDA must police and sanction in its regulatory capacity. There are already concerns about the FDA’s objectivity,⁸⁷ and saddling the FDA with the responsibility of developing bioethics regulations could introduce additional conflicts of interest.

As shown above, the Executive Branch has not been a source of robust bioethics policy. Presidential initiatives like the NBAC conducted extensive hearings and made recommendations on difficult topics such as cloning and stem cells, but its advisory nature and lack of implementation capacity prevented its work from becoming more firmly ensconced as lasting policy. President Bush’s Council on Bioethics has similar limitations; moreover, the Council may have trouble gaining widespread legitimacy because of the perception

⁸⁶Christine Willgoos, *FDA Regulation: An Answer to the Questions of Human Cloning and Germline Gene Therapy*, 27 AM. J.L. & MED. 101, 124 (2001). See also Fukuyama, *supra* note 21:

The FDA is not set up to make politically sensitive decisions concerning the point at which selection for characteristics like intelligence or height cease to be therapeutic and become enhancing, or whether such selection can be considered therapeutic at all. The only grounds on which the FDA can prohibit a procedure are effectiveness and safety. But there will be many safe and effective procedures in the coming biotechnology revolution that will nonetheless require regulatory scrutiny.

⁸⁷Elliott, *supra* note 36. Elliott argues that the FDA is “deeply compromised” by industry money because the pharmaceutical industry pays user fees to the FDA in order to expedite product review. Similarly, Richard Horton, editor of the prestigious journal *The Lancet*, laments that the FDA is the “servant of the drug industry.”

that it is ideologically biased. Efforts by Executive agencies to regulate controversial biotechnologies have also been less than successful. The RAC is the only group which consistently asks normative ethical questions; however, its mandate is limited to gene splicing technology, and it currently has very little actual authority. Although the FDA inherited regulatory control over gene splicing from the RAC and has recently and dubiously asserted jurisdiction over cloning, the FDA does not appear to be well-suited to undertake the type of bioethical inquiry which these technologies demand.

Federal government – Congress

Despite several attempts to pass human cloning legislation, Congress has been unable to do so. Following the Dolly announcement, legislators rushed to introduce measures to regulate human cloning. Although there was widespread agreement that something needed to be done, Congress could not agree on what to do. Nine separate proposals were drafted and considered, but ultimately none of them was enacted. It will always be difficult to craft a cloning bill because of the polarized positions on the issue. On one hand, right-to-life proponents and other allied groups seek a broad ban on all cloning, while on the other hand, patient advocates and the scientific community favor a more limited ban which allows potentially beneficial research to continue. Beyond the inherent difficulty of reconciling such incompatible views, the challenges of drafting legislative language contributed to the demise of these bills. Some of these bills were sloppily written, perhaps because of the haste with which they were drafted. For example, the Ehlers bill proposed to prohibit “the use of a human somatic cell for the process of producing a human clone” but neglected to define “somatic cell” or “human clone.”⁸⁸ Other bills were handicapped by loopholes. The Campbell, Bond, and Lott bills were intended to prohibit all cloning practices, but their imprecise language would have

⁸⁸Willgoos, *supra* note 86, at 116. H.R. 922 and 923, 105th Cong (1997).

allowed certain cloning practices to continue.⁸⁹

In 2001, the announcement by a biotechnology company, Advanced Cell Technologies, that it had successfully cloned a human embryo prompted Congress to renew its efforts to pass cloning legislation. In July 2001, the House resoundingly passed (265-162) a bill which prohibits both reproductive and therapeutic cloning and makes it a crime to sell or use any treatments which use cloning techniques.⁹⁰ In turn, Republicans in the Senate introduced a bill which would place a six-month moratorium on all cloning until the Senate could consider the issue more carefully. To force a quicker vote on the moratorium, it was bundled with other, unrelated measures, including a proposal to allow drilling in the Arctic National Wildlife Refuge and a provision for railroad workers' retirement benefits.⁹¹ The Senate failed to take up the moratorium because it was tied to these other contentious measures.

Recently, the Senate revived the cloning issue and began debating a proposal similar to the House bill which passed in July 2001. The Senate is deeply divided, with many members worried that the measure closes the door too strongly on potentially beneficial research. As Senator Feinstein (D-CA) said, "This is a very promising field of research... [Passing the bill would be] like throwing the baby out with the bathwater."⁹² The vote is so close that the likely outcome remains unclear.⁹³

This brief history of cloning legislation in Congress demonstrates the limitations of the legislative process for bioethics policy. In particular, legislation tends to be crisis-driven rather than proactive. Given Congress' huge breadth of responsibilities, it is understandable that Congress tends to react only after some major event has brought an issue to its attention; however, this limitation of Congress is particularly troublesome

⁸⁹*Id.* at 116. S. 1574, 105th Cong. (1998); S. 1599, 105th Cong. (1998); S. 1601, 105th Cong. (1998).

⁹⁰Sheryl Gay Stolberg, *House Backs Ban on Human Cloning for Any Objective*, N.Y. TIMES, Aug. 1, 2001, at A1. The bill makes cloning a crime punishable by up to ten years in prison.

⁹¹Sheryl Gay Stolberg, *Senate Declines to Take Up Proposed Cloning Moratorium*, N.Y. TIMES.COM, Dec. 4, 2001.

⁹²Sheryl Gay Stolberg, *Bush Rallies Opponents of Cloning*, N.Y. TIMES.COM, Apr. 10, 2002.

⁹³*Id.*

for bioethical issues because they require careful thought. As one writer notes:

[T]hose engaged in public policy and ethical discourse must struggle to understand the new science or technology, as well as the implications of these scientific developments for society. Therefore, not only does ethical deliberation begin much too late, but it also develops more slowly...

Informed and thorough ethical discussion addresses both the present and future applications of technology and science. In fact, a common role for ethicists and policymakers alike is to speculate on future applications and implications associated with scientific innovation. This speculation requires time not often afforded those charged with shaping the development of bioethics policy or law.⁹⁴

The intense pressure to respond quickly to high-visibility events means that legislative proposals may not be drafted as thoughtfully as possible. Furthermore, in the haste to consider them, these proposals may be coupled with other, unrelated measures which can derail bioethics proposals for reasons aside from their intrinsic merit. Congress' failure to pass cloning legislation is a case study in the difficulty of taking legislative action, even when there is widespread consensus that some action is necessary.

State legislation

State legislatures also responded to the Dolly announcement by proposing laws to outlaw human reproductive cloning. Nearly thirty states considered legislation, and several states eventually enacted measures. California was the pioneer with the California Cloning Act,⁹⁵ which imposed a five-year ban on human reproductive cloning. Michigan passed a similar law shortly thereafter⁹⁶ and also prohibited the use of state funds for cloning research.⁹⁷ Rhode Island has also outlawed reproductive cloning,⁹⁸ and Missouri proscribed

⁹⁵CAL. HEALTH & SAFETY CODE §§ 24185 *et seq.* (West 1997). The statute defines cloning as the "practice of creating or attempting to create a human being by transferring the nucleus from a human cell from whatever source into a human egg cell from which the nucleus has been removed for the purpose of [sic], or to implant, the resulting product to initiate a pregnancy that could result in the birth of a human being." § 24185(c). *See also* CAL. BUS. & PROF. CODE §§ 2260.5, 16004, 16105 (West 1997), which proscribe cloning practices as unprofessional conduct and provide for revocation of licenses for violations of cloning laws.

⁹⁶MICH. COMP. LAWS ANN. §§ 333.16274 *et seq.* (West 1998).

⁹⁷MICH. COMP. LAWS ANN. §§ 333.26401 *et seq.* (West 1998).

⁹⁸R.I. GEN. LAWS § 23-16.4-2 (1998).

the use of state funds for reproductive cloning purposes.⁹⁹ More recently, Louisiana enacted a five-year ban on reproductive cloning,¹⁰⁰ and Virginia has proscribed the practice indefinitely.¹⁰¹

Religious positions

Religion occupies an important, yet uncomfortable, place in bioethical debate. Religion provides the vocabulary and doctrinal tools to articulate and consider questions about whether scientifically feasible activities are ethically permissible. At the same time, the heterogeneity of religious views tends to complicate, rather than simplify, bioethical debate. As one writer observes:

We live in an increasingly pluralistic society. Within all Western countries there is no longer a single shared set of moral values. Even the various religions disagree on ethical matters and many people no longer accept any religious teaching... Nevertheless, there is still great value in taking seriously the various traditions – religious and otherwise – that have given rise to ethical conclusions. People do not live their lives in isolation; they grow up within particular moral traditions.¹⁰²

A brief survey of some different denominations' views on stem cell research demonstrates the extent of variation across religious traditions. On one hand, there are absolute positions such as those taken by the Catholic and Greek Orthodox Churches. Catholics, who believe that life begins at conception, are opposed to stem cell research and any other biotechnologies which involve manipulation of embryos. As Pope John Paul II said in 2001, "A free and virtuous society, which America aspires to be, must reject practices that devalue and violate human life at any stage from conception until natural death."¹⁰³ Although the Greek Orthodox Church does not view an embryo as a life, the Church believes that an embryo's "strong residue of the God-given likeness" prohibits manipulation. According to a clergyman at the Holy Cross School of Theology, "[T]he establishment of embryonic stem cell lines was done at the cost of human lives. Even though

⁹⁹MO. ANN. STAT. § 1.217 (West 1998).

¹⁰⁰LA. REV. STAT. ANN. § 1299.36.2 (West 1999). Part D provides that violations shall be punishable by fines of up to \$10 million and/or imprisonment, with or without hard labor, for up to ten years.

¹⁰¹VA. CODE ANN. § 32.1-162.22 (2001).

¹⁰³*The Stem Cell Debate: The Embryonic Journey and Its Milestones*, N.Y. TIMES, Dec. 18, 2001, at F4.

not yet a human person, an embryo should not be used for or sacrificed in experimentation, no matter how noble the goal may seem.”¹⁰⁴

In contrast, other religious traditions take a less absolute position. Islam views an embryo as a “drop of matter” until ensoulment occurs at 120 days; therefore, most Sunni and Shiite Muslims endorse carefully regulated embryonic stem cell research for therapeutic purposes, as long as it is conducted before ensoulment occurs.¹⁰⁵ Judaism views an embryo as a potential life worthy of some degree of special consideration; however, an embryo has no legal status under Jewish law and is not considered part of a human being until implanted in the womb.¹⁰⁶ Thus Judaism does not proscribe the *in vitro* cultivation of embryos for stem cells.¹⁰⁷ Despite the difficulty of reconciling different religious traditions, religion – or at least moral concepts which can be generalized from religious thought without relying on any particular religious authority – has a role in bioethical debate. Many religious ideas are consonant with background ethical beliefs that are shared, to at least some degree, by most people in society.

It has also been challenging to incorporate religious discourse into bioethics debates because of the strong secular bias in public policy conversations. As one writer describes:

¹⁰⁴*Id.*

¹⁰⁵*Id.*

¹⁰⁶*Id.*

¹⁰⁷Tully, *supra* note 20, at 1403. The Jewish faith also condones cloning for certain therapeutic purposes and for reproductive purposes under extraordinary circumstances, e.g., a sterile, last-in-line descendant of a family killed during the Holocaust. Generally, however, most religious leaders are opposed to cloning. See, e.g., June 1997 NBAC Report, available in <<http://bioethics.georgetown.edu/nbac/pubs.html>> (visited Apr. 8, 2002).

In bioethics discourse in North America, particularly when public policy or law is addressed, it is typically assumed that acceptable arguments must meet a standard of rationality, secularity, and empirical demonstrability that excludes religion. On this assumption, participants in the debate must shed particularistic identities and commitments and enter into a realm of neutrality in which only what is rationally self-evident to all, empirically demonstrated, or clearly derived from, and coherent with existing laws and practices, will govern the public regulation of research and clinical medicine.¹⁰⁸

Thus the challenge is to couch religious themes in terms that can be integrated into public policy discussion. Just as scientists must try to make biotechnology accessible to non-scientists, the religious community must aspire to universalize its contributions to bioethical debate. In a recent book on religious ethics in genetic science, the author urges religious leaders to be more concrete and practical in their policy views. Instead of making categorical, general statements such as “humans and animals are creations of God [and therefore] should not be patented as human inventions,”¹⁰⁹ she suggests that they take a more nuanced view which acknowledges that the market and scientific freedom have some role in improving human welfare. She further suggests that religious leaders try to formulate policy alternatives which incorporate theological concerns.¹¹⁰

The scientific community

Although some accuse the scientific community of being essentially amoral,¹¹¹ scientists have voiced many concerns about the consequences of biotechnological progress. For example, the academic and industrial research communities have observed a voluntary moratorium on germline gene therapy for over a decade.¹¹²

With respect to cloning, Professor Wilmut, who led the team which cloned Dolly, admitted that he is uneasy about where cloning could ultimately go and believes that it is morally irresponsible that the United States

¹⁰⁹Quoting the 1995 Joint Appeal Against Human and Animal Patenting.

¹¹⁰Lisa Sowle Cahill, Untitled, THEOLOGY TODAY, Vol. 58, Issue 4, Jan. 1, 2002, available in 2002 WL 13417544 (reviewing Audrey Chapman, UNPRECEDENTED CHOICES: RELIGIOUS ETHICS AT THE FRONTIERS OF GENETIC SCIENCE (1999)). Chapman also criticizes religious leaders for making policy recommendations which are reactive, rather than looking forward to technologies which are on the horizon.

¹¹¹Robinson, *supra* note 30, at 10-11: “Not only do scientists have precious little to say about how we should live, but scientists themselves have distressingly poor track records with respect to recognizing any moral constraints on their activities.”

¹¹²See BIO website <www.bio.org/er/ethics.asp> (visited Apr. 8, 2002). Germline gene therapy is the manipulation of the DNA sequence of an embryo to remove an undesirable gene or insert a desirable gene. By successfully changing the gene sequence in the embryo, scientists can ensure that all of the adult cells will have the altered sequence.

has not yet instituted a ban on human cloning. The National Academy of Sciences (NAS) recently completed a study on human cloning, which signaled that the scientific community recognized the need for bioethical consideration. In its report issued in early 2002,¹¹³ NAS concluded that Congress should outlaw human reproductive cloning for at least five years because current techniques are dangerous and likely to fail.¹¹⁴ The Academy did not consider whether reproductive cloning should be allowed if it were to become medically safe, acknowledging that in this instance a broad national dialogue on the social and ethical implications of cloning would be needed. Although the authors of the NAS report recognized that the report's conclusions were couched in the language of safety and capability rather than morality and ethics, the report represents a genuine effort by the scientific community to contribute to the development of bioethical standards.

At the same time, scientists themselves have doubts about whether bioethical concerns can rein in scientific progress. Professor Lu, the scientist who leads cloning efforts in China, is personally opposed to human reproductive cloning, but she suspects that the technology will eventually go there. "It is an irresistible trend," she says.¹¹⁵ The forefathers of the nuclear bomb noted the same tendency. Robert Oppenheimer once said, "[There is a] cult of progress which ensures that science will proceed with little conscience and few restraints... When you see something that is technically sweet you go ahead and do it."¹¹⁶ His colleague, John von Neumann, echoed, "Technological possibilities are irresistible to man."¹¹⁷

¹¹³Committee on Science, Engineering, and Public Policy, National Research Council, *Scientific and Medical Aspects of Human Reproductive Cloning* (2002), available in <<http://books.nap.edu/books/0309076374/html/index.html>> (visited Apr. 8, 2002).

¹¹⁴NAS identified several dangers with current cloning technology. Experiments in five mammalian species (sheep, cattle, pigs, goats, and mice) have had very low success rates. Many clones die *in utero* or shortly after birth, and the surviving clones often have significant birth defects. Female animals carrying cloned fetuses also face risks, including death from cloning-related complications. Human cloning efforts are likely to entail similar, if not greater, risks.

The Academy did not see the same degree of danger for therapeutic cloning and therefore concluded that therapeutic cloning research could continue, although the NAS panel encouraged further discussion of the normative issues around this research.

¹¹⁵Leggett and Regalado, *supra* note 16.

¹¹⁶*Id.*

¹¹⁷Cahill, *supra* note 108, at 495.

As this section shows, there have been many disparate efforts to articulate bioethical principles, regulations, and laws, but few definitive norms have crystallized. Bioethics today is in a cacophonous state. Different parties talk at, rather than to, each other, and efforts to coordinate these parties in an interdisciplinary way have not yielded tangible results thus far. To change this *status quo*, bioethical discussion must be conducted in a more fruitful way.

Section II: Why Bioethical Standards Are Particularly Important for Modern Biotechnology

The field of bioethics is not new. It has existed for quite some time to address the dilemmas raised by advances in medical science, from the distribution of transplantable organs to the enactment of living wills. In some respects, these previous dilemmas resemble the issues raised by modern biotechnology. For instance, the advent of life support technology asked society to determine the proper balance between an individual's autonomy to determine his or her own fate and medical technology's capability to sustain his or her life indefinitely. Similarly, genetic screening technology challenges society to decide whether an unborn child with a genetic predisposition to early-onset cancer has an autonomous right to be born, despite biomedicine's ability to detect and screen out this risky trait. Both situations raise uncomfortable concerns that scientists and doctors can "play God" with interventions which enable them to sustain or end life.

Despite some similarities in general principles and rhetoric, however, the types of bioethical concerns raised by modern biotechnologies are significantly different in degree and kind from those which society has grappled with thus far. Biotechnologies demand more caution because they are likely to affect many more people than previous medical advances. For example, a limited number of patients end up on life support or require an organ transplant, whereas a stem cell-based cancer therapy would be relevant to many more people. Also, because genetic techniques involve manipulation of the code which is the fundamental basis of humanity and individuality, the ethical considerations are of a completely different nature than those for more traditional interventions. There is a clear distinction, for example, between a risky surgical procedure to correct a rare, neonatal heart condition and a "therapy" which involves the screening out of embryos with genes linked to the condition. The following section aims to more fully articulate these and other rationales for developing

clearer and more uniform bioethical principles.

Moral and philosophical qualms

A fundamental moral concern about genetic technologies is that the human genome is sacrosanct and thus should not be manipulated. This belief has been expressed in many ways, from a religion-based view that an embryo which embodies a unique genetic combination is life itself, to a more pantheistic notion that there is sanctity in man's relationship with nature which imparts an obligation not to interfere with the "natural" gene pool. In addition to these philosophical qualms, there are practical reasons to worry about meddling with the gene pool. One may be skeptical of whether scientists can outwit Darwinism, and one can reasonably worry that scientists might unwittingly induce genetic modifications that will ultimately reduce, rather than enhance, humans' capacity to adapt and survive. Cloning, for example, enables reproduction without the recombination of genes, and it is possible that widespread cloning could lead to detrimental mutations or concentration of undesirable traits.¹¹⁸

Even if scientists could manipulate the genome with perfect safety, however, there are several other reasons that society may feel uncomfortable with these practices. First, the ability to change the genome may alter society's tolerance for individual variations. As philosopher of science Philip Kitcher notes, "Once we have left the garden of genetic innocence, some form of eugenics is inescapable."¹¹⁹ Scientists have already identified the genes for several traits, and they will undoubtedly pinpoint more. They will also learn to modify them. William Safire's question is therefore an appropriate one to ask: "How far should we go in

¹¹⁸Another example is the gene for sickle-cell anemia, which also promotes resistance to malaria. Consider, for example, a genetic intervention which successfully eliminates sickle-cell anemia but detrimentally lowers the capacity to ward off malaria.

¹¹⁹Brave, *supra* note 19.

extending our lives, in freeing bounded minds, in defiantly removing all crimson birthmarks to perfect our bodies?”¹²⁰

At the same time, it is important to avoid excessively deterministic assumptions about the extent to which genetics can dictate the way people look or behave. Although some traits are a function of a finite number of genes, most of the traits which account for a person’s unique personality and physical characteristics are polygenic – i.e., governed by many genes. So many genes may be involved that science may never be able to fully identify or understand the interactions among all of them. Moreover, the expression of these genes is affected by the array of environmental influences that a person encounters over his or her lifetime. As a result, science’s ability to produce a “made-to-order” person is inherently limited. As one writer states,

I reject the genetic determinism implicit in the... human dignity argument. The clone and the cloner will not be identical... They will grow up in different environments and encounter divergent life experiences and peers. Random events, such a luck and chance, as well as life choices and free will, will play a role in the development of the clone’s personality, character, behavior, and intellectual capabilities.¹²¹

Even so, history bears witness to the fact that man has tried to engage in eugenics many times in the past, and genetic tools are the most powerful yet for the eugenically minded.

Some also worry that biotechnology could lead to the objectification of human life. This fear may be most acute in a therapeutic cloning scenario where a child is cloned as a source of tissue for the parent – i.e., a “spare organ bank.” In the reproductive cloning context, some argue that the parent of a cloned child may unreasonably expect the child to strongly resemble himself or herself, rather than allowing and encouraging the cloned child to develop his or her own identity.¹²²

¹²⁰William Safire, *The Crimson Birthmark*, N.Y. TIMES.COM, Jan. 21, 2002. Safire’s question refers to the Nathaniel Hawthorne short story, “The Birthmark,” in which a scientist who is obsessed by a small birthmark on his wife’s cheek, “a crimson stain upon the snow,” administers a remedy to correct it which ends up killing her.

¹²²Cahill, *supra* note 108, at 492-93.

Cloning may also challenge society's conception of the traditional family structure. Cloning would make it possible for a woman to have a child without a genetic contribution from a man, and a man could have a child without a genetic contribution from a woman as long as he has access to a surrogate womb. Fukuyama foresees that cloning "will establish... unnatural relationships between parents and children. A cloned child will have a very asymmetrical relationship with his or her parents. He or she will be both child and twin of the parent from whom his or her genes come, but will not be related to the other parent in any way."¹²³

While these potential threats to society's notions of individuality and the family should not be taken lightly, they must be evaluated in a measured way. For example, the outcry over cloning children as "spare organ banks" may be more hypothetical than realistic. Therapeutic cloning does not involve the gestation and birth of children from whom tissues could be harvested. Rather, therapeutic cloning refers to the practice of cloning embryos in order to extract stem cells,¹²⁴ which are then grown into tissues in a laboratory. With respect to reproductive cloning, it not clear how much demand there would actually be for cloned offspring. Even if there were fairly widespread demand,¹²⁵ the fears that clones will be treated differently by society and by parents may be overstated. As society becomes more informed about and familiar with cloning, it may develop less objectionable expectations about cloned children. After all, identical twins share the same genetic sequence, but society and their parents do not expect the twins to be the same, nor do they view each twin as a less unique individual person because there is a genetic copy of that person. Similarly, a child who is an exact genetic copy of a parent cannot, and should not, be expected to become an identical person.

¹²³Fukuyama, *supra* note 21.

¹²⁴Stem cells are harvested when embryos consist of approximately 300 cells.

¹²⁵There does not appear to be tremendous desire for cloned children at this time, but the literature identifies potential sources of demand as infertile parents who would prefer to clone rather than adopt, homosexual couples, the last member of a family who wishes to perpetuate his or her lineage (e.g., Holocaust survivor).

The implications of cloning for the family structure may also not be so different from changes which society has already tolerated. As one writer notes:

For me, human cloning represents another in the existing array of assisted reproductive techniques...

I am willing to slide down the slippery slope of assisted reproduction practices deviating from the traditional concept of reproduction, which include medical treatment of infertility, artificial insemination, in vitro fertilization, and surrogate motherhood. Cloning merely represents an incremental step beyond these technological advances which have changed our notion of reproduction...

[T]he genie is already out of the bottle today with respect to the non-nuclear family. The past several decades have witnessed a remarkable transformation of the “family”... Although we should encourage the formation of traditional families and help them remain intact, we should respect the value of personal choice [to opt for a non-traditional family].¹²⁶

Another concern about some biotechnologies is that they could exacerbate inequalities in society. This position envisions that the socio-economically fortunate will have access to techniques which refine their genomes and thereby solidify their social and intellectual advantages, whereas the less fortunate will be unable to afford these technologies and thus fall even further behind. As one author observes:

It is a matter of human and cultural fact that people want to have babies and want to give them all the advantages in life they can afford. In the absence of restrictions on other ways the wealthy can equip their children for a privileged life, it is difficult to envision limits on the marketing of benefits like genetic enhancement, projected to be available soon via ‘reprogenetics.’... Not only would the poor and uninsured be excluded from these choices, they may well continue to lack basic health care and other important necessities like decent public education.¹²⁷

While equity concerns deserve serious consideration, it is not clear whether they should halt scientific progress. After all, genetics may provide cheaper ways to treat certain conditions and thereby make benefits more, rather than less, widely available. According to the libertarian view espoused by one writer:

We should not allow our fears of the distributional consequences of genetic enhancement to limit technological advancements, including human cloning. First, the specter of social inequities is congruent with other choices modern capitalistic society allows parents. Today, affluent parents can offer their children all sorts of environmental enhancement, from summer camps to the latest computer technology, from music lessons to a first rate college education. Second, the cost of genetic enhancement may drop substantially in the future and come within the reach of average or even poor couples or individuals.¹²⁸

Clearly, there are deep moral and philosophical schisms on the propriety of various biotechnologies. These differences of opinion emanate from firmly held beliefs which are not readily amenable to rational discussion and resolution. On one hand, opponents of cloning, stem cells, and other controversial biotechnologies – a coalition of diverse groups encompassing pro-life activists to environmentalists – view these technologies as fundamentally, unconditionally wrong. On the other hand, patient advocates, scientists, and the biotechnology industry are just as passionately convinced that these technologies are a force for good. Indeed, some argue that it would be morally derelict for scientists to refrain from seeking as much knowledge as possible to heal the sick and improve the human condition.

Unresolved, these differences of opinion will perpetuate an unease about biotechnology which society can ill afford. The unending controversy over abortion is an instructive parallel. Although the Supreme Court decided that abortion is legal under certain circumstances, Americans remain bitterly divided. Abortion foes continue to try to restrict the practice, with extreme activists even resorting to violence to underscore their beliefs. Abortion supporters work vigilantly to maintain the legality of the practice and uneasily recognize that a slight shift in the composition of the Supreme Court could lead to a ban on the procedure. Since biotechnology is likely to be relevant to far more people than abortion is, and since biotechnology implicates a much broader range of ethical and philosophical concerns, the consequences of allowing bioethical differences to fester could be very problematic.

To some extent, science may discover alternatives which enable society to enjoy the benefits of biomedical progress without getting mired in ethical dilemmas. For example, finding a way to use stem cells from bone

marrow, umbilical cord, or adult cells instead of embryonic stem cells would obviate questions about whether it is proper to manipulate embryos.¹²⁹ Scientific solutions are likely to go only so far, however, and society will not be able to escape the need to make some difficult bioethical decisions. The lines of bioethics policy will not be easy to draw, but with concerted effort it should be possible. As one writer urges,

[T]o say the line's exact location is unclear does not mean it does not exist or cannot be drawn. Can anyone really believe there is no way to distinguish, morally or legally, between preventing a vicious disease such as Alzheimer's and seeking to make a better piano player? Saying so is the wrong approach to a technology that offers such hope.¹³⁰

Deterrence and norm articulation

In addition to the substantive reasons outlined above, there are what might be described as “symbolic” reasons to systematically develop bioethics policies. The effort to articulate policies would, in and of itself, serve as a statement that society views biotechnologies as materially different from previous medical advances. As Fukuyama notes, “It is important to lay down at an early point a political marker that will demonstrate that the development of these technologies is not inevitable, and that societies can exercise some measure of control over the pace and scope of technological advance.”¹³¹ Fukuyama's political marker is particularly important in light of the powerful forces that are driving biomedical progress forward.

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The competitive nature of biomedical research fuels scientific progress. In order to distinguish themselves

¹²⁹ *On Human Embryos and Medical Research: An Appeal for Ethically Responsible Science and Public Policy*, 16 ISSUES L. AND MED. 261, 266-67 (2001). These alternative sources of stem cells are already being used in certain cancer treatments and are being investigated for leukemia and other diseases. See also Vernon J. Ehlers, *The Case Against Human Cloning*, 27 HOFSTRA L. REV. 523, 530 (1999): “Because of the ethical and moral concerns raised by the use of embryos for research purposes it would be far more desirable to explore the direct use of human cells of adult origin to produce specialized cells or tissues for transplantation into patients.”

¹³¹ Fukuyama, *supra* note 21.

and to attract research funding, scientists continue to push the bounds of what is technologically possible. Countries can also get caught up in the pursuit of scientific supremacy. As observed by Nobel Laureate Paul Berg:

To many Western scientists, China's leap into embryo cloning [for therapeutic stem cell harvesting] lends credence to their argument that the technology is all but unstoppable, despite any ethical objections it might raise. Some even predict that fears of falling behind in a biotech race with China could spur the U.S. to set aside some of its misgivings... We will either condemn [the Chinese] as godless members of an evil empire, or we will say, "Hey, wait a second, we can't be left out of this race."¹³²

Furthermore, scientific progress is unpredictable. Science often advances through serendipitous, unexpected discoveries, and since today's bioscience is global, well-funded, and equipped with the latest technological capabilities, breakthroughs are literally possible at any time.

Thus science has a "Pandora's Box" tendency. It has an innate momentum which can lead to the rapid advancement of technology without thorough consideration of the moral or societal consequences, and once capabilities become available, it is difficult – perhaps impossible – to fully contain them. An illustrative example is the continuing proliferation of nuclear weapons, despite strenuous efforts to eliminate them. Therefore, as one writer urges, "[O]pen dialogue among members of scientific, philosophical, ethical, and general communities at large is crucial before the 'biomedical genies' are released from their bottles – not afterwards."¹³³

The need for pre-emptive bioethical norms is particularly acute because of the very fine – perhaps non-existent – line between biotechnology for good and biotechnology for misuse. Scientific progress is usually motivated by the best of intentions – i.e., to develop therapies for debilitating illnesses. As one writer explains, however, "[t]he reality is that once we discover the means to manipulate DNA for therapeutic purposes in our drive to cure disease, we will have discovered the means for manipulating DNA for any

¹³³Smith, *supra* note 31, at 102.

other purpose, such as genetic enhancement or even, as some have suggested, incorporating genes from other species into the human genome.”¹³⁴ Moreover, there will always be renegade scientists who deliberately engage in morally dubious work. For example, Chicago biophysicist Dr. Seed alarmed people everywhere when he announced in 1998 that he intended to clone himself as the first cloned human being. Similarly, European doctors Panos Zavos and Severino Antinori prompted renewed worries when they declared in 2001 that they planned to set up an international consortium to clone humans within two years.¹³⁵ Obviously, the availability of bioethical norms would be particularly useful for condemning the activities of scientists like Dr. Seed.

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The profound power of market forces is another reason to establish *ex ante* bioethical norms. As more and more money is invested in scientific research, research becomes an end in itself and ethical debate tends to be muted. As one writer describes, the market can confer ethical acceptability by default: “Financial imperatives will conspire with technological imperatives to confer upon cloning a societal legitimacy that, as a moral matter, it will never have earned.”¹³⁶ One example is the system of gene patenting. Because biotechnology companies, which desire patents to secure the value of their research investments, successfully pushed to establish the practice of gene patenting, there is no longer a window of opportunity to discuss the propriety of owning pieces of the genome.

¹³⁴Brave, *supra* note 19.

¹³⁵Rumors from an article in The Gulf News, an English language newspaper in the United Arab Emirates, have suggested that Dr. Antinori has helped a woman become eight weeks pregnant with a cloned embryo; however, these rumors have not been confirmed. Stolberg, *supra*, at note 68.

¹³⁶Robinson, *supra* note 30, at 13.

The influence of the market is a particularly relevant consideration for biotechnology because a significant amount of innovation is expected to occur within for-profit, private companies. In the past, when the federal government was the predominant source of funding for cutting-edge research, scientific developments could be monitored and, if necessary, regulated by attaching restrictions to those funds.¹³⁷ When research is conducted within private companies, there is no easy way to observe or control it.¹³⁸ Private, for-profit companies are unlikely to be forthcoming about their activities, since disclosure could vitiate their competitive position in the marketplace; moreover, private companies have tremendous incentives to disregard fuzzy ethical questions if doing so will benefit their bottom line. As the director of the bioethics program at the University of Miami warns, “Mind you, what’s wrong with the *in vitro* fertilization industry is precisely what’s going to go wrong with the stem cell industry, namely, it’s heavily privatized and it’s not regulated.”¹³⁹

Finally, it is important to remember that these profit-seeking companies can exist only because they are responding to tremendous demands in the marketplace. Biotechnology is attractive to people who are desperate for hope and help. Patients afflicted with debilitating diseases like Parkinson’s disease and terminal cancer are hungry for cures. Similarly, there seem to be few limits to the amount of effort and expense which infertile couples are willing to incur in order to have a child, as evidenced by the growth of the lucrative artificial reproductive technologies (ART) industry. People may even have a voracious appetite for medical interventions which are not essential to health, as the burgeoning field of cosmetic surgery suggests. As long

¹³⁷Even those entities which traditionally relied on federal funds, e.g., universities, are not insulated from the market imperative. Since the 1980 Bayh-Dole Act, which allowed universities to patent their discoveries and license them out for commercialization, many universities have become more closely intertwined with the biotech industry. In 1999, universities filed for 7,612 patents, executed 3,295 licenses, and received adjusted gross licensing income of \$641 million. See Brave, *supra* note 19, at 7. See also Fukuyama, *supra* note 21, who points out that the nature of the scientific community has changed. While at one time the scientific pioneers were “pure” scientists in universities, there are few academic researchers today without some links to the biotechnology industry or even explicit commercial interests in certain technologies.

¹³⁸Stolberg, *supra* note 35. An example of private companies’ secrecy is the experience of Glenn McGee, a philosopher and assistant professor of bioethics at the University of Pennsylvania. McGee resigned from the ethics board of Advanced Cell Technologies because he felt that the privately held company was too secretive. Shortly thereafter, a newspaper reporter asked Professor McGee to comment on an animal cloning experiment which was being conducted by a company which the reporter could not reveal. The company turned out to be Advanced Cell Technologies. Even as a recent member of the ethics board, McGee had been unaware of this experiment.

¹³⁹*Face to Face: [Interview with] Ken Goodman, Bioethicist, Discusses Stem Cell Research, Cloning, HMOs and More*, S. FLA. SUN-SENTINEL, Sept. 23, 2001, available in 2001 WL 22757369.

as there is robust demand for medical – and perhaps even non-medical – uses of biotechnology, companies will strive to meet that demand.

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Ex ante bioethical standards could also lead to the more economically efficient use of research and development resources. Today, ethical discussions, regulation, and law typically emerge only after a scientific advance has occurred – i.e., only after millions of dollars and many years of effort have been invested in coaxing a scientific genie out of its bottle. If biotechnology companies had some advance notice about which technologies and applications are likely to be regulated, they could order their research priorities and development activities accordingly. When there is uncertainty about the regulatory environment, companies may act more hastily than would be ideal. For example, the CEO of Advanced Cell Technologies indicated that the company felt compelled to report its cloning findings sooner because it anticipated that Congress might move to restrict this research:

There's one big variable here, and that's the U.S. Congress... Given that we have regulations in the United States that prevent [cloning], we felt that we should go forward and publish this scientific result so scientists can have this data. Time is of the essence for people who are dying of life-threatening disease. We want to apply these technologies as fast as we can – of course, with appropriate debate, appropriate oversight.¹⁴⁰

Ironically, by rushing to make its announcement, Advanced Cell Technologies may have made it more difficult to have appropriate debate and oversight.

Another economic factor which may deserve a place in bioethical debate is whether there should be restrictions on technologies which could unduly strain the health care financing system. As many health economists and policy-makers have concluded, one major reason for the escalating cost of health care in the United States

is the proliferation of sophisticated technology.¹⁴¹ While some biotechnological innovations will be extremely cost-effective, some biotechnological interventions could be the next generation of “runaway technologies” which raise the costs of health care for all. The high cost of health care already makes basic medical coverage unaffordable for a substantial fraction of the population, so the possibility that biotechnology may further widen the gap in health care access warrants some thought, especially if some of these “runaway technologies” are also ethically dubious ones. Bioethical standards could be useful for preventing costly and ethically questionable technologies from multiplying.

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To some extent, there is a prisoner’s dilemma in the regulation of biotechnology; therefore, without bioethical standards, scientific and market imperatives could conspire to create a “race to the bottom.” For example, many countries feel that it is proper to ban human reproductive cloning, but they also recognize the financial benefits of allowing it, e.g., investment dollars and tax revenue which come from hosting biotechnology companies. Unless most countries agree to regulate or ban cloning, any single country’s attempt to halt its development will be ineffective, since research can move relatively easily to a more hospitable regulatory environment. As Fukuyama notes, “In the absence of [] international agreements, any nation that chooses to place limits on internal development will simply give other nations a leg up.”¹⁴²

As a country with tremendous political and financial clout, and as the most biotechnologically advanced

¹⁴¹The proliferation of technology tends to drive up health care costs, largely through excessive utilization. The CAT scan is an oft-cited example of an innovation which is overused, rather than employed only when truly necessary. *See, e.g.*, Chapter Two of HENRY AARON, *SERIOUS & UNSTABLE CONDITION* (1991).

¹⁴²Fukuyama, *supra* note 21. *See also* Greene, *supra* note 29, at 359-60. A similar prisoner’s dilemma was the impetus for the adoption of multinational fair labor standards.

nation in the world, the United States is in a position to halt – or at least slow – this race to the bottom. Although it could be difficult to coordinate international action on bioethical issues, the United States can exercise leadership simply by adopting standards domestically. As Fukuyama points out:

Regulation never starts at an international level. Nations have to develop rules for their own societies before they can even begin to think about creating an international regulatory system. This is particularly true in the case of a politically, economically, and culturally dominant country like the United States. Other countries around the world will pay a great deal of attention to what the United States does in its domestic law. If an international consensus on the regulation of certain biotechnologies is ever to take shape, it is unlikely to come about in the absence of American action at the domestic level.¹⁴³

Given the United States' ability to be so influential in setting global bioethical norms, the United States may even have some degree of responsibility to act. According to one writer, "The failure of the United States [to ban human cloning] does not only affect this nation. Rather, it represents a missed opportunity."¹⁴⁴

For all of the reasons discussed above, the development of ethical norms is particularly important for modern biotechnology.¹⁴⁵ The period when *ad hoc* advisory and study commissions were sufficient has ended; more concrete and systematic action is now necessary. Although science is advancing rapidly, most scientists estimate that the first wave of "genomic knowledge and power" is at least a decade away.¹⁴⁶ This period of time provides a fortunate window of opportunity for thoughtful bioethical discussion and the implementation of appropriate regulatory structures.

This endeavor must not be entered into lightly. It will be exceedingly difficult, if not impossible, to fully agree on the principles for regulation; moreover, new forms of regulation can be costly, not only financially but also in the sense that missteps could dissipate confidence that any meaningful and workable regulation is possible.

¹⁴⁴Greene, *supra* note 29, at 361.

¹⁴⁵It is important to note that there may be some bioethical issues which can appropriately be left to more individualized determinations. These issues must be consciously and systematically identified, however, and not left to individualized determination simply because there is no policy-making structure in place.

¹⁴⁶Although most of the genome has been sequenced, it will take years to figure out the function of newly discovered genes and to devise ways of manipulating them.

Nevertheless, it is time for society to squarely face these issues. As Fukuyama comments, “Regulation brings with it many inefficiencies and even pathologies. But in the end, there are certain types of social problems that can only be addressed through formal government control, and biotechnology is one of them.”¹⁴⁷

¹⁴⁷Fukuyama, *supra* note 21.

Section III: Consideration of Different Decision Making Options

If bioethical norms are essential, then the next question is how to develop these norms. Although it would be convenient to employ existing regulatory structures, they have been inadequate to date, as discussed in Section I. Arguably, advances in biotechnology have outgrown the current regulatory regime, leaving what Fukuyama calls “gaping holes” that legislatures and administrative agencies around the world have been racing to fill.¹⁴⁸ There is no institution in the United States which has comprehensive jurisdiction over biotechnology, and this fragmentation in the regulatory regime is not ideal. Many bioethical issues are relevant to more than one technology, and because many technologies are used in tandem, dispersed regulatory efforts will hamper the development of a consistent set of bioethical principles. For example, cloning and germline gene therapy have been addressed by different agencies,¹⁴⁹ even though scientists are likely to use cloning and gene therapy together.¹⁵⁰

One potential response to this situation is to modify and strengthen existing institutions. This approach takes advantage of structures and mechanisms which are already in place, e.g., the FDA’s well-established process which requires researchers to submit research proposals and gain approval before clinical trials can begin. It is an appealing idea to merely add on a bioethics component to these established structures and mechanisms, and one writer proposes such an institution – i.e., an FDA-RAC where both agencies have been legislatively strengthened to have real and coordinated authority over all biotechnologies.¹⁵¹

¹⁴⁸ *Id.*

¹⁴⁹ As discussed above, current cloning policy was determined by President Bush and has been implemented through restrictions on federal funding by the NIH. On the other hand, gene therapy research is regulated by the FDA and, to some limited degree, the RAC. There are no explicitly articulated principles which connect or integrate these regulations, and the regulatory processes for cloning and gene therapy do not interact with each other. *See, e.g.*, Knowles, *supra* note 94, at 19.

¹⁵⁰ Cloning can increase the efficiency of gene therapy by allowing scientists to produce several copies of a genetically treated embryo and thereby increase the number of times that scientists can try to implant the embryo in the uterus.

¹⁵¹ Willgoos, *supra* note 86, at 124.

Arguably, a better approach is to craft an entirely new process and institution. As discussed above, the establishment of a novel entity would send a strong message that these bioethics policies are distinct from other types of regulations. A separate institution would also allow resources and attention to be fully focused on bioethical issues. Given the complexity of these issues and the speed at which scientific advances occur, there is no doubt that a dedicated institution would be more effective than an institution which already has many other responsibilities. Finally, a new entity enables a “fresh start,” free of legacy organizational cultures and histories which may hamper novel thinking. Changed circumstances sometimes call for entirely new measures. For example, Congress established the Federal Aviation Administration (FAA) to oversee air transportation, even though the Interstate Commerce Commission (ICC) was already in place to regulate other, ground-based forms of transportation. Because the considerations for airplanes were so different from those for cars and trains, a new agency was deemed necessary. Similarly, the ethical challenges of biotechnology warrant a new institution. Of course, any new institution can and should incorporate the useful features of existing ones, but its structure and capabilities should be determined by what will be most appropriate for its particular mission. The following section therefore considers the advantages and disadvantages of different types of institutions.

An initial consideration is whether bioethics policy should be set at the national or state level. Some argue that states should regulate biotechnology because they traditionally regulate medical practice. It may indeed be appropriate to leave some subset of bioethical issues to state-by-state determination, since this approach allows local community values to be reflected more precisely in bioethics policies. There are several reasons that nationally uniform policies are desirable for most bioethical issues, however.¹⁵² From a practical point

¹⁵²U.S. Congress, Office of Technology Assessment, *Biomedical Ethics in U.S. Public Policy – Background Paper* (U.S. GPO, Washington, D.C.), June 1993, at 27. Congress asked the Office of Technology Assessment (OTA) to analyze previous bioethics commissions’ strengths and weaknesses in order to inform any efforts to establish bioethics bodies in the future. In its report to Congress, the OTA noted “a strong sentiment” on the need for federal, rather than local, action.

of view, it may be difficult for states to access the extensive information and expertise needed to set bioethics policy. Also, because biotechnology is quite portable, any norm could be relatively useless if it is not at a federal level. Without consistency across states, a “race to the bottom” within the United States would always be possible. As one author expressed, “If forty states ban cloning, the research will take place in the other ten.”¹⁵³ Finally, uniform national standards may actually be preferable for researchers and biotechnology companies. They will not have to comply with 50 different sets of regulations, and a single set of guidelines sends a clearer signal about what is and is not acceptable. Moreover, researchers and developers can plan their activities with less uncertainty about whether the policy in a particular state will change at some point in the future. For all of these reasons, national standards are likely to be more efficient and effective.

Of the many possible sources of federal policy, Presidential initiatives and the judicial system are probably least suitable. In some respects, the President’s involvement in the development of bioethics policy can be beneficial. The President has a unique ability to raise the profile of an issue and can add momentum to the policy-making process;¹⁵⁴ however, the President’s proximity is also a fatal hazard. Even if a Presidential initiative is designed in a way which is intended to minimize political partisanship, there will always be questions about its independence. Consider, for example, the criticism that has been leveled at President Bush’s Council on Bioethics: “Whether it’s the White House’s widely publicized concern for the Catholic vote in key electoral states in making its stem-cell decision... what’s depressingly clear is that the political, market and media forces so familiar to us are now shaping the future of the human genome.”¹⁵⁵

The judicial system is also not a suitable institution because it is inherently reactive. Courts can consider

¹⁵³Robinson, *supra* note 30, at 13.

¹⁵⁴Joseph Palca, *A New National Bioethics Commission – Maybe*, THE HASTINGS CENTER REPORT, Vol. 26, No. 1, Jan. 11, 1996, available in 1996 WL 10189220. Assessing the potential effectiveness of the NBAC, Palca says, “There are a few more encouraging signs for NBAC. First, it will exist inside the White House, rather than being assigned to an executive department. Any agency that doesn’t play ball with NBAC risks annoying the president and his top advisers.”

¹⁵⁵Brave, *supra* note 19.

issues only when they are raised by litigants, and courts can decide issues only within the context of the specific factual situations which are presented to them. Also, procedural rules and overburdened court dockets can drag out litigation for months and even years, and this pace is too slow for quickly-changing science. Finally, the common law nature of the American judicial system means that policy consensus emerges only gradually, as disparate decisions from different jurisdictions are reconciled by higher courts. Moreover, there is no guarantee of finality even after the Supreme Court has decided an issue, as illustrated by the continuing controversy over *Roe v. Wade*.¹⁵⁶

More sensible places for the development of bioethics policy are in Congress or in a new regulatory agency. The primary advantages of leaving policy-making responsibility to Congress are its plenary authority and its ability to act quickly, if and when it wants to do so. A regulatory agency's authority is limited to those areas which have been granted to it, and it must open up proposed regulations for a notice and comment period before it can enact them.¹⁵⁷ In contrast, Congress can implement policy as soon as it can draft legislation and muster sufficient votes to pass it. Of course, it is a widely known and lamented fact that Congress moves anything but quickly on most matters, and there is little reason to think that Congress will act differently on bioethics issues. After all, even after high-profile events fostered widespread agreement that something should be done about cloning and gene therapy, Congress was unable to pass any legislation.¹⁵⁸

¹⁵⁶410 U.S. 959; 93 S. Ct. 1409; 35 L. Ed. 2d 694 (1973).

An additional consideration is that courts are likely to encounter a difficulty which they have faced in other science-related contexts, namely, the "battle of the experts." As long ago as the 1970s, a presidential advisory group convened by President Ford issued a report which addressed the problem of how policy issues could be resolved when experts had divergent opinions. The group proposed a "science court" which would supplement and assist regular courts, similar to the way magistrate courts operate. The "science court" would conduct public adversary hearings, which would be moderated by three disinterested referees. The "adversaries" would be scientists with different points of view, while the "judges" would be scientists who were appointed based on recommendations from scientific societies and other professional organizations. The judges would catalog the points of agreement and disagreement and then suggest specific research projects to settle the areas of disagreement. See Smith, *supra* note 31, at 107.

¹⁵⁷Administrative Procedure Act § 553, 556-57.

¹⁵⁸Congress' futile efforts to pass cloning legislation have been recounted in Section I above. When a relatively healthy, 18-year-old volunteer died during a gene therapy clinical trial at the University of Pennsylvania, there was extensive concern

There are several reasons that Congress failed to act at these times, and these constraints are likely to hamper Congress' ability to set bioethics policy in the future. As discussed above, consensus on bioethical issues is elusive under any circumstances, but particularly so in Congress' politically charged environment; furthermore, it is challenging to draft unambiguous legislative language which specifically proscribes certain practices without chilling potentially beneficial ones. According to one author's assessment of Congress' gridlock in 1997, "The current federal legislative stalemate over human cloning prohibitions exemplifies the virtually impossible task of devising statutory language acceptable to both the scientific community and the pro-life community."¹⁵⁹

In addition to these factors, Congress has so many responsibilities that its attention to bioethics policy is prone to be waylaid at any time. For example, the full Senate had been considering cloning legislation when the September 11th terrorist attacks occurred. Justifiably, the Senate set aside cloning to address more pressing matters, but this type of spasmodic deliberation, which is intrinsic to Congress, is not conducive to the prudent formation of bioethics policy. Congress' hectic schedule also means that legislation may be passed too hurriedly, without giving a fair hearing to all important considerations, and such rushed legislation could end up being more harmful than helpful.¹⁶⁰

that regulatory oversight had failed. Several influential legislators, including Senators Kennedy and Frist and Congressman Waxman, threatened to act, but ultimately they did not. See Rainsbury, *supra* note 70, at 595.

¹⁵⁹Rokosz, *supra* note 78, at 489.

¹⁶⁰See, e.g., Chang Ai-Lien Natalie Soh, *Early Days for Law on Ethical Problems in Research*, The Singapore Straits Times, Sept. 22, 2001, available in 2001 WL 26056933. As one member of Singapore's Bioethics Advisory Committee commented, "Legislation should be made only after the issues have been discussed publicly and a consensus reached on what should be done."

See also Reiss, *supra* note 102, at 91. "Such a consensus should be based on reason and democratic debate and take into account long established practices of ethical reasoning... [C]onsensus should not be equated with majority voting. Consideration needs to be given to the interests of minorities, particularly if they are especially affected by the outcomes, and to those – such as young children, the mentally infirm, and non-humans – unable to participate in the decision-making process."

Another real challenge for Congress is that bioethics policy demands a degree of technical expertise which requires effort to attain and maintain. Although many bioethical questions are conducive to general understanding and debate, many other questions will be more opaque to most legislators, who do not have backgrounds in the biological sciences. Because there are so many demands on legislators' time, many will not have the opportunity to fully grasp relevant technical details before they are asked to vote on legislation. As one writer describes, this technical hurdle can make bioethics policy rather perplexing for legislators:

Here your senator faces the same difficulties as your bishop. Cloning is hard to understand, as is stem cell research and xenotransplantation. Neither your senator nor your bishop is likely to be a biologist and neither are the people closest to them likely to have much scientific expertise. But when conscientious legislators look outside of their intimate circle of advisors for advice on cloning and its regulation, they are likely to encounter the cacophony that I described previously. Their scientific advisors will be long on technique and short on moral analysis, and their religious advisors will argue among themselves on the correct morals and be as fuzzy on specifics as the legislators themselves are.¹⁶¹

Also, given the high rate of turnover in the membership of Congress and its staff, it is difficult to envision how bioethics-related knowledge can be accumulated effectively by Congress as an institution, either by a critical mass of legislators or within a relevant Congressional committee.

Finally, Congress may be a perilous place for bioethics policy because of the vagaries of political power and the peculiarities of legislative procedure. Powerful individuals can play decisive roles in the fate of legislation. For example, the chairperson of a committee has a heavy hand in determining what form a bill takes and whether it will get out of committee for general floor debate. Similarly, the minority and majority leaders in each chamber of Congress have considerable leverage to build or destroy support for a piece of legislation. Like these individuals who have inordinate power, organized special interest groups can sway the Congressional process to a degree that is disproportionate to the weight that should properly be given to their interests. Furthermore, the legislative process can derail bioethics policy for reasons unrelated to its

substantive merit. Disparate pieces of legislation are often cobbled together and consolidated in one large bill. As a result, a bioethics portion of a bill may be subject to negotiation so that the entire package can pass, or even if a majority agrees with a bioethics portion of a bill, it may be rejected because the overall package was not compelling enough to pass.¹⁶²

For all of these reasons, it seems unlikely that Congress will be able to produce thoughtful bioethics policies on a timely, consistent basis. In the characteristically blunt words of Professor Richard Posner, “Waiting for legislative blueprints to map out the perimeters of the New Biology is... an almost certain guarantee for egregious delays and disappointments.”¹⁶³

¹⁶²Curt Anderson, *Senate KOs Broad Gene Bias Measure*, AP ONLINE, June 29, 2000, *available in* 2000 WL 23361313. The genetic privacy bill is an example of this dynamic. Following the announcement about the sequencing of the human genome, there was a flurry of concern about the discriminatory use of genetic information by employers and insurance companies. As a result, several senators proposed measures which would limit the use of genetic information. These measures were proposed as amendments to the annual appropriations bill for the Departments of Labor, Education, and Health and Human Services. President Clinton threatened to veto the entire appropriations bill because of the bill’s overall spending level and a variety of other reasons unrelated to the privacy provision.

¹⁶³Smith, *supra* note 31, at 117-18.

Where Congress has limitations, a regulatory agency has corresponding advantages. A key benefit of a regulatory agency is that it can respond more nimbly to fast moving science. Once Congress passes a law, the law gathers an inertia and presumptive legitimacy which raises the barriers to changing it. Although Congress can build flexibility into its laws through devices such as “sunset provisions,” which trigger reconsideration after a certain period of time, this reconsideration is time-consuming and repeatedly exposes policy to the whims of the legislative process. Although a regulatory agency must follow notice and comment procedures to promulgate regulations, this process tends to be less arduous than the legislative process.¹⁶⁴ Moreover, an agency can promptly initiate modifications to regulations when necessary. Although regulatory modifications may also require notice and comment, this process is generally less torturous than the legislative amendment process. This flexibility is critically important when initial regulations appear to be having unintended, undesirable effects or when circumstances change. With respect to the latter, it is instructive to remember that practices which were once very controversial, such as organ transplants and in vitro fertilization, have gained widespread acceptance over time.¹⁶⁵ A bioethics institution must be capable of adapting to these types of attitude shifts.

Another benefit of a regulatory agency is that it can accumulate technical expertise. A bioethics agency would undoubtedly be populated by several people with extensive scientific training, and others in the agency who do not have such training would absorb the necessary knowledge over time. Relative to Congress, where members must be re-elected to stay in office, the level of turnover at regulatory agencies is lower. As a result, people within a regulatory agency can build broad and deep bases of knowledge. A regulatory agency also gains expertise through its intimate oversight of a particular industry. It can gather extensive information about what is happening “on the ground,” and if one believes that more information generally leads to better policy, a regulatory agency is well suited to develop bioethics policy.

Finally, a regulatory agency may be more capable than Congress of protecting the privacy of participants in the biotechnology industry. This consideration would be particularly relevant to private companies or

¹⁶⁴See, e.g., Willgoos, *supra* note 86, at 122.

¹⁶⁵Reiss, *supra* note 102, at 82.

renegade scientists. The prospect of public disclosure will motivate parties to be secretive in order to preserve competitive secrets, avoid moral outcry, or both.¹⁶⁶ Unfortunately, the most secretive parties are likely to be the ones which warrant the most careful ethical scrutiny, so the ability to keep information confidential is important to engender as much disclosure as possible. Although regulatory agencies and Congress are both government entities which are subject to FOIA disclosure requirements, a regulatory agency is generally better able to protect information from widespread exposure. Most Congressional hearings are open to the public and are a matter of public record. Although closed hearings are possible, it would be difficult for a biotechnology company to request one without immediately raising some eyebrows. In contrast, the findings of a regulatory agency are not routinely published,¹⁶⁷ and an agency could assure that information provided for policy development purposes would not be identifiably disclosed.

As the preceding discussion indicates, there are many factors to consider in conceiving of a novel bioethics institution. No institutional structure will be perfect. Despite the strengths and virtues of any particular institution, it will have weaknesses and imperfections as well. Therefore the most important point is to formulate an institution as thoughtfully as possible, and then establish it as soon as possible, so that it is in place and ready to address the ethical questions raised by the next major biotechnological advance.

¹⁶⁶Rainsbury, *supra* note 70, at 599. Describing trends in the gene therapy field, Rainsbury notes: The public nature of the RAC has had a salutary effect in informing the public about the progress of gene therapy... Today, gene therapy is in a transition period. The field has shown enough promise to induce private firms to begin sponsoring studies. If such investment is to be encouraged, however, regulators must guarantee investigators that proprietary information will be treated confidentially. Otherwise, competing firms will be able to free-ride on the substantial investment of pioneering firms, deterring investment... [R]equiring public disclosure of all information submitted to FDA likely would have a chilling effect on such submissions.

¹⁶⁷This statement refers to information that a bioethics agency might seek from private companies about what types of research they are conducting in order to determine whether rulemaking is necessary. This type of information need not be published, e.g., in the Federal Register. This statement does not refer to information which the agency can and should disclose, e.g., companies whose activities have violated established regulations.

Section IV: A Proposal for an Institution Dedicated to the Development and Implementation of Bioethics Policy

Taking the considerations from the previous sections into account, this section offers a concrete proposal for a bioethics policy institution called the Agency for the Genetic Technologies Community (AGTC).¹⁶⁸ The AGTC is a standing organization which can give sustained focus to bioethics issues,¹⁶⁹ and it is exclusively devoted to the development and implementation of bioethics policy. Its mission is two-fold: to provide a politically neutral and inclusive forum for the debate of bioethical questions and to implement and enforce bioethics policy. The AGTC's structure mirrors its two-part mission. The deliberative element of the AGTC is vested in a leadership council, which bears responsibility for facilitating discussions of bioethical issues and crystallizing these discussions into regulations or legislative recommendations. Enforcement is carried out by career staff members of the AGTC.

The AGTC addresses several factors which have hampered more effective resolution of bioethics issues thus far. First, the AGTC shall serve as a focal point where diverse points of view can converge. As noted previously, the parties in bioethical debates tend to have a hard time talking to each other. As one writer describes:

¹⁶⁸The word "community" in this name is intended to recognize the broad range of parties which have interests in bioethics policy and which are represented within the institution. Although the acronym is not particularly elegant, it contains the same initials as the four bases of the DNA sequence.

¹⁶⁹OTA report, *supra* note 152, at 30-31. The OTA reported a widespread belief that *ad hoc* initiatives are the least desirable way to address bioethical issues. Restarting *ad hoc* initiatives consumes valuable time, money, and personal energy, and the knowledge and credibility that each initiative gathers is dissipated when it dissolves. By contrast, a standing body can accumulate expertise and legitimacy and transfer these valuable assets from issue to issue. The OTA also noted that the United States is unusual in its lack of a continuous bioethics organization. Most other countries with bioethics institutions have established permanent ones. *Id.* at 29.

It remains true... that as a sociological matter, it is the rare scientist who is equally at home in scientific discourse and religious discourse when he or she is addressing the morality of a scientifically feasible project. If is true, furthermore, as a conceptual and methodological matter, that it is only with the greatest difficulty that scientific and religious thought mesh once we leave the plane of high abstractions and descend to the level of concrete problems.¹⁷⁰

The tremendous challenge of finding common vocabularies and assumptions will be ameliorated, to at least some degree, by establishing the AGTC as a place where all of these parties interact on a continuous basis. Moreover, the AGTC will bring order to the currently fragmented regulatory regime. As discussed above, several different agencies have – or claim to have – jurisdiction over certain bioethical issues, and these ambiguities in the lines of responsibility are unwieldy. As the “owner” of bioethics issues, the AGTC clarifies any confusion about responsibility or jurisdiction and minimizes duplication and inconsistency in the policy-making process.¹⁷¹

Placement within the government

An institution’s placement within the government is a key determinant of its effectiveness, and there are at least two possibilities for the AGTC. One of the more obvious options is to tuck it into the Department of Health and Human Services (HHS). Since the NIH and FDA, which are components of HHS,¹⁷² already have excellent reputations within the scientific and medical communities, and since there may be some synergies between the AGTC and these agencies, it could be sensible to place the AGTC within HHS. This placement would have several drawbacks, however. First, the AGTC may get buried in the vast HHS bureaucracy, where potential “turf battles” and competition for resources among HHS agencies could hinder the AGTC’s

¹⁷¹The bioethical issues associated with any technologies which are currently within the jurisdiction of another agency should be transferred to the AGTC. For example, stem cell guidelines, which are currently promulgated by the NIH, would become an AGTC responsibility. Similarly, the RAC’s functions would be folded into the AGTC, and although the FDA could continue to oversee the safety aspects of gene therapy experiments, the AGTC would have exclusive authority over the bioethical rules for gene therapy.

¹⁷²See <www.hhs.gov/about/orgchart.html> (visited Apr. 8, 2002) for an HHS organization chart.

effectiveness.¹⁷³ Second, the AGTC may be perceived as a “techy” and scientifically oriented body like the NIH, rather than the inclusive, multidisciplinary institution it is intended to be.

A more promising option is to set up the AGTC as an adjunct to Congress, similar to the Congressional Budget Office (CBO)¹⁷⁴ and General Accounting Office (GAO).¹⁷⁵ These offices were established by Congress to provide independent and nonpartisan assessments to assist Congress with its legislative activities. Despite their direct involvement with Congress, these offices have maintained their political neutrality and have established themselves as respected, credible sources of information and policy recommendations. Similarly, the AGTC would provide bioethics information and policy recommendations to Congress. As an adjunct agency, the AGTC would have ready access to the legislative process if and when bioethics laws are necessary, yet it can still maintain the autonomy and credibility which are so vital to its mission.

Membership of the AGTC

The composition of the AGTC is another crucial factor in maintaining its autonomy and credibility. In particular, the members of the leadership council must include a broad array of constituencies so that the policies it develops will incorporate – and just as importantly, be perceived as incorporating – all salient considerations. For similar reasons, the members must be adequately diverse along ethnic, gender, and geographic lines. As the OTA report indicated, “Diversity in race, ethnicity, gender, and professional experience is a paramount factor in appointing commissioners and staff. Ethics involves values, and a commission with

¹⁷³For example, competition for scarce HHS resources was a factor in the decision to dismantle the RAC and fold it into the FDA.

¹⁷⁴See <www.cbo.gov> (visited Apr. 8, 2002). The Congressional Budget Office (CBO) was created in 1974 to provide Congress with objective, timely, and nonpartisan analyses, information, and estimates needed for economic and budget decisions. The CBO is a professional, nonpartisan organization and does not make policy recommendations, but rather presents Congress with options to consider.

¹⁷⁵See <www.gao.gov> (visited Apr. 8, 2002). The General Accounting Office (GAO), commonly called the investigative arm of Congress or the Congressional “watchdog,” responds to Congressional requests for studies of the federal government’s programs and expenditures. The GAO examines how the federal government spends taxpayer funds, advises Congress and the heads of agencies about how to make government more effective and responsible, evaluates federal programs, audits federal expenditures, and issues legal opinions. It also recommends actions to improve government operations.

monolithic membership or staffing cannot hope to adequately represent the diverse range of perspectives in American society.”¹⁷⁶

While inclusion is critical, the leadership council must also be kept to a manageable size. Using the NBAC and Council on Bioethics as benchmarks, a size of fifteen to twenty members seems to be reasonable. For organizational purposes and in situations where one person needs to speak for the AGTC, it would be expedient to designate one person as the chair of the leadership council. The chair shall be elected by the other council members and serve a two-year term.

The next consideration is which fields should be represented on the leadership council.¹⁷⁷ One author proposes an allocation of one-third government interests, one-third scientific community, and one-third ethicists, theologians, economists, and representatives of “other disciplines that represent society’s many concerns.”¹⁷⁸ For the NBAC, it was required by Executive Order that at least one member be selected from each of the following five disciplines: philosophy/theology, law, social/behavioral science, medicine/allied health professions, and biological research.¹⁷⁹ Although the Council on Bioethics does not have such an explicit requirement, these five fields are represented on the Council. The AGTC’s leadership council should undoubtedly include basic science, medicine, public health, law, ethics, philosophy, theology, and economics; however, the council should also include representatives of biotechnology companies¹⁸⁰ and patients. Pa-

¹⁷⁶OTA report, *supra* note 152, at 34.

¹⁷⁷Knowles, *supra* note 94, at 19-20. In explaining why multidisciplinary representation is crucial, Knowles states: Not only does the lack of integrated ethical, scientific, and policy debates affect the ethical background of regulatory responses, but it also affects the laws drafted under these circumstances. Such laws tend to be narrowly drafted and reactive, rather than broadly drafted, dynamic, and capable of adapting to scientific advances that tend to follow quickly on the heels of one another. There is scant recognition of any interaction between new and existing technologies in related fields [e.g., reproductive and genetic technologies]... laws may be drafted too vaguely, broadly, or narrowly so as to inhibit the development of scientific innovation.

¹⁷⁸Greene, *supra* note 29, at 357.

¹⁷⁹Exec. Order No. 13,137 (1999), available in <http://bioethics.georgetown.edu/nbac/nbac_extended.html> (visited Apr. 8, 2002). In §2, this order specified that at least three members should be selected from the general public to “bring[] to the Commission expertise other than that listed.” It further provided that the number of scientist and non-scientist members should be approximately equal and that close attention should be given to geographic distribution and ethnic and gender diversity.

¹⁸⁰Many bioethicists believe that cutting-edge science is going to be done in private companies, not in public institutions where federal funds can be controlled. As Arthur Caplan said, “A bioethics that is disconnected from industry is a bioethics that flies blind.” See Stolberg, *supra* note 35. The NBAC included some representatives of biotechnology companies, but the Council on Bioethics does not.

tient advocates were absent from previous bioethics commissions, and it is hard to imagine that balanced and credible bioethics policy can be developed without their input. It may also be appropriate to include one or two members from the legislative and regulatory communities to provide insights on the practical implications of various policy alternatives. After all, the leadership council should not look like a think tank, as the Council on Bioethics, which is populated almost entirely by professors, does. Rather, the leadership council's orientation should be academic and deliberative, yet simultaneously pragmatic and geared toward implementation.¹⁸¹

To further ensure the AGTC's autonomy and credibility, the process of appointing the leadership council must be insulated from political partisanship as much as possible. One step is to accept nominations for the leadership council from the public at large. Doing so would dampen the opportunity for political leaders to use these positions as a way of thanking those who have supported them politically or of installing those who will hew to their ideological agenda. From among these nominees, the members of the leadership council will be chosen by a bipartisan group of Congressional leaders – the Speaker of the House, the President *pro tempore* of the Senate, and the minority and majority leaders of the House and Senate.¹⁸² Since the AGTC is an adjunct to Congress, and since the AGTC may make legislative recommendations to Congress, it is sensible for Congressional leaders to pick the members of the leadership council. To prevent the council from being inordinately shaped by the political landscape of any particular session of Congress, however, council members shall serve staggered, four-year terms.¹⁸³ As additional safeguards against partisanship, it could

¹⁸¹OTA report, *supra* note 152, at 34. The report recommended that a bioethics body should include both practitioners and theoreticians.

¹⁸²OTA report, *supra* note 152, at 35. The CBO Director is selected in a similar way. The Speaker of the House and the President *pro tempore* of the Senate select the Director based on recommendations by the budget committees of both chambers of Congress.

¹⁸³The members of the NBAC served two-year terms, although several members remained on the Commission for several terms. The members of the Council on Bioethics are slated to serve two-year terms. Members of previous bioethics commission, e.g., the National Commission, served four-year terms. For the AGTC, four years seems to be a reasonable term for ensuring a beneficial amount of continuity without obligating members to serve for an excessively long time. See, e.g., OTA report, *supra* note 152, at 35: "Infusing new ideas and personalities by limiting members' terms carries some cost... Commission dynamics

be mandated that no more than half of the council members can be from the same political party¹⁸⁴ and that members are removable only for neglect of duty or malfeasance in office.

Rule-making authority

To prevent the AGTC from becoming just another advisory commission or “debating society,” the leadership council must have some rule-making authority. Given the nuances of bioethical issues and the dynamic nature of scientific progress, the AGTC should have three types of authority. First, it can issue non-binding guidelines. Second, it can draft and recommend legislation to Congress. Third, it can act as a regulatory agency by promulgating and enforcing administrative rules. To implement any of these three measures, the leadership council must muster a two-thirds vote. This two-thirds requirement seems to be more appropriate than a simple majority because it is desirable to reach a meaningful degree of consensus on divisive bioethical issues, and a stricter standard will push the leadership council to seek more common ground. Moreover, the rules which emerge from the AGTC will be regarded more seriously because they have surmounted this higher hurdle.

Non-binding guidelines, the “softest” type of action that the AGTC can take, are appropriate for nascent developments where the trajectory of a technology and its ethical implications are not entirely clear. Non-binding guidelines would outline general normative principles to guide research and development, and these guidelines would also serve as notice that more specific regulations could follow in the future. An example

take some time to develop; overly short term lengths would strain the consensus building process.”

¹⁸⁴The U.S. Commission on Civil Rights uses this type of measure to ensure political neutrality. See <www.usccr.gov> (visited Apr. 8, 2002). The U.S. Civil Rights Commission is an independent, bipartisan, fact-finding agency established under the Civil Rights Act of 1957. Its responsibilities are to investigate complaints of discrimination; study & collect information about discrimination; analyze federal laws and policies; serve as a national clearinghouse for information about discrimination or denial of equal protection of the laws; submit reports, findings, and recommendations to the President and Congress; and issue public service announcements to discourage discrimination or denial of equal protection of the laws.

of a situation where non-binding guidelines would be appropriate is genetic screening. Genetic screening is currently used to detect embryos with dispositions for grave, incurable diseases; however, this technique may be employed in the future for the ethically questionable purpose of screening embryos for traits such as height and athletic ability. AGTC guidelines would serve the useful purpose of articulating the general principle that screening technologies should be used for therapeutic, rather than elective, applications.

When a situation is serious enough to warrant a strong measure or when the path of a technology has become more evident, the leadership council may deem it appropriate to make legislative recommendations to Congress. For reasons discussed previously, e.g., the inflexibility of statutory language, Congressional action is most appropriate for marking the outer bounds of ethically proscribed conduct. As expressed by one writer:

[T]hrough the law, our society does not attempt to agree upon all conduct which is ethical, and all conduct which is unethical. Law performs a much narrower function. In the universe of ethics, right and wrong behaviors lie along a spectrum, with ethically good or even ideal conduct at one end and ethically bad behavior at the other end... Society often uses law to identify those behaviors primarily at one end of the spectrum: those behaviors about which there is general agreement that they are unethical, wrong, or unacceptable... But that leaves much conduct... simply not addressed by law, and over which there may be significant differences of opinion... it does not address the ethical maximums.¹⁸⁵

Human germline gene therapy is an example of a context where legislation may be suitable. Many scientists have called for a presumptive ban on germline gene therapy to mark a strong ethical line. As Eric Lander, director of the genome center at MIT, recommends:

I would have... an absolute ban in place on human germline gene therapy. Not because I think for sure we should never cross that threshold, but because I think that it is such a fateful threshold to cross that I'd like society to have to rebut that presumption someday, to have to repeal a ban when it thought it was time to ever try something like that.¹⁸⁶

The leadership council's involvement in recommending and drafting legislation could increase the chances that Congress will be able to pass bioethics laws. As discussed above, the drafting of appropriate language has been a bottleneck during previous attempts to legislate. Although the language in any AGTC proposal will – and should – encounter challenges and negotiations in Congress, an AGTC proposal may shortcut enough political wrangling to prevent the legislative process from being stymied at the drafting stage.¹⁸⁷ Ideally, the imprimatur of the AGTC would also have a persuasive influence on the legislative process. If the AGTC successfully establishes its credibility as a source of thoughtful, nonpartisan, and fact-based bioethics policies, legislators are likely to show more deference to AGTC recommendations. As a result, bioethics legislation may have a better chance of passing through Congress.

The third type of authority that the AGTC should have is a regulatory body's ability to promulgate and enforce administrative rules. These rules would be most appropriate in situations where a specific kind of research and development is considered to be ethically permissible, but only with certain restrictions or safeguards. For example, embryonic stem cell research is an area where regulation is proper because an outright legislative ban would be too restrictive, whereas non-binding guidelines would not be restrictive enough. Like FDA regulations, AGTC regulations would apply to both public and private entities, and the AGTC should be empowered to enforce them on a case-by-case basis. Case-by-case review will not only ensure adherence with these rules, but also enable AGTC to craft better regulations. As one author explains,

¹⁸⁷OTA report, *supra* note 152, at 27: "Government-sanctioned commissions allow debates about contentious issues to go forward in a somewhat less politicized way than is possible on the floors of Congress... [they] provide a vehicle to handle issues that are amenable to consensus building... [and] can be an opportunity to create the environment in which political action becomes possible by gathering policy relevant information and injecting it directly into the policy matrix. In doing so, commissions can often consider controversial issues independent of the regular political process and its constraints."

the RAC's analysis of individual cases enhanced its effectiveness as a deliberative body:

Unlike other federal bioethics advisory committees, the RAC involved itself directly in the review of specific human gene therapy experiments. Rather than debate grand propositions about human dignity, RAC meetings got down to the nitty-gritty of the scientific details for the reviewed protocols. Although this often lent a 'schizophrenic' quality to meetings, with lay members of the RAC largely unable to participate in technical discussions, it did focus attention on the real costs and benefits of proceeding with a controversial science. This appears to have had [] positive consequences...

[C]ase-by-case evaluation revealed the human interests at stake in the enterprise. It is one thing to say in the abstract that a certain class of human clinical trials is off-limits; it is quite another to reject a treatment for which desperate volunteers have already lined up.¹⁸⁸

Since rules are toothless without effective enforcement, the AGTC must have enforcement capabilities, staff, and resources. At a minimum, the AGTC should establish an approval process for relevant research and development protocols, similar to that of the FDA or the initial incarnation of the RAC.¹⁸⁹ If necessary, the AGTC may also impose reporting obligations and oversight committees; however, these measures should be used only sparingly to avoid excessively onerous bureaucratic requirements. Finally, the AGTC should be authorized to impose civil and criminal sanctions for violations of its rules.

AGTC responsibilities

In addition to developing and enforcing rules, the AGTC shall fulfill several other important responsibilities. More specifically, the AGTC will gather and distribute information, sponsor discussion forums, educate the general public, and act as the primary liaison to the global bioethics community. These responsibilities will be carried out primarily by AGTC staff, but with the guidance and participation of the leadership council.

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¹⁸⁹In some instances, the AGTC may want to explore the feasibility of coordinating its approval process with the FDA's to minimize the amount of additional paperwork for researchers and biotechnology companies.

A crucial function of the AGTC is to be the authoritative source of information related to bioethics. This role will lend a tremendous amount of credibility to the AGTC as an organization and to the policies it develops. Also, if bioethics policy is to become less crisis-driven and more proactive,¹⁹⁰ the AGTC must continually update its awareness of biotechnological developments. It is critical that the AGTC be effective at collecting information about activities in both the public and private sectors.¹⁹¹ Although private parties are generally hesitant to come forward with information about their activities, they may be more forthcoming if the AGTC ensures confidentiality and if they believe that the information gathering is “fair” – i.e., that all other parties are also reporting their activities. Ironically, private actors may feel most compelled to cooperate with the AGTC if the AGTC successfully establishes itself as an effective regulatory body. As one writer notes:

[N]on-funded firms or institutions are likely to seek some sort of regulatory imprimatur if they are at the vanguard of ethics and technology. An easy way to establish public confidence in a product is to have it cleared by a trusted institution... In addition to positive public relations, non-federally-funded institutions may submit voluntarily to [] review in order to shield themselves from liability in the event that something untoward happens in the course of the clinical trial. Although such a regulatory compliance defense probably would not be dispositive, it certainly would be evidence that the investigators had behaved cautiously and prudently.¹⁹²

As another aspect of its role as a repository of information, the AGTC should also disseminate information. Although the AGTC must be cautious to avoid disclosing any confidential information, it could publicly distribute useful baseline information, e.g., an annual report or quarterly fact sheet which contains general findings about biotechnological developments, as well as what the AGTC has done – or plans to do – about them. In addition, the AGTC should set up an archive, with a small staff of librarians, to serve

¹⁹⁰Knowles, *supra* note 94, at 22. As Knowles describes, one of the weaknesses of current bioethics policy is its reactive tendency: “New developments take us by surprise because we are not discussing these issues prospectively. We respond by using law in a reactive, *ad hoc* manner, not anticipating that we may in fact ultimately restrict scientific progress, including applications from which many may benefit.”

¹⁹¹As discussed above, the balance of publicly vs. privately funded research has increasingly tilted toward the private side. *See, e.g.*, Fukuyama, *supra* note 21. Until the early 1990s, most biomedical research was funded through the NIH or other federal agencies. *See also* Brave, *supra* note 19. As Caplan predicts, “I think the genetic revolution is going to be privatized and going to be a business. It is simply inevitable.”

as a reliable source of more detailed information for parties involved with bioethics issues, e.g., legislators, lawyers, biotechnology companies, journalists.

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To promote open, interdisciplinary discussion of bioethical issues, the AGTC shall sponsor public conferences at least once a year, but more frequently if appropriate. The leadership council will determine a salient topic or set of topics for each conference, and each member of the leadership council will be responsible for ensuring that the major interest groups in his or her substantive area send representatives to the conference. The proceedings of each conference will be recorded and placed in the public record. Although conferences with some discussion of bioethical issues are already being held, the AGTC conferences are still useful and necessary. First, these conferences will reliably occur on a regular basis, and their agenda will be exclusively dedicated to bioethical issues. Also, because these conferences are AGTC-sponsored, they are likely to draw a broader group of participants than conferences hosted by more specialized groups, such as an industry association or religious organization. Finally, with the legitimacy of the AGTC behind them, these conferences are likely to become the primary forum for the bioethics community – i.e., a place where leaders in bioethics can expect to interact and where influential policy discussions will occur.

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Another essential duty of the AGTC is to ensure that the general public is sufficiently informed to develop thoughtful opinions about bioethical issues. There are several reasons to devote AGTC resources to this

task. First, democratic values require the public to be aware of issues which could affect them directly and intimately. As Dr. Sydney Brenner, Distinguished Professor at the Salk Institute of Biological Studies and the “father of molecular genetics,” asserts, “The public needs to be involved. They are part of the issues.”¹⁹³ As another writer argues, “If we wish to stand by our democratic belief in the right of people to participate in choosing their destiny, the most pressing task is to educate the public and its elected representatives.”¹⁹⁴

There are also practical advantages to a better-informed public. A policy developed with meaningful public input is likely to be a better policy. For example, during Oregon’s effort to prioritize health services for Medicaid funding, the Oregon Health Services Committee proposed an initial ranking based primarily on cost-benefit calculations. After public criticism arose, the Committee held open meetings to elicit public comments. Based on these comments, the Committee revised the list, and the revised list was widely acknowledged to be a better one.¹⁹⁵

Finally, if the public is not well informed, bioethical issues are prone to be discussed in sensationalized terms. With many divisive social issues, attention-grabbing slogans, images, and symbols tend to define the terms of debate, and since science-related issues can easily be misunderstood, the chances of emotionally-driven, exaggerated bioethics discourse are very high. Consider, for example, the strategy of Dr. Leon Kass, President Bush’s personal bioethics adviser and chair of the Council on Bioethics. Although Dr. Kass has acknowledged that the actual demand for human reproductive cloning is quite low, he has explicitly indicated that he plans to use the reproductive cloning issue as a “unique practical opportunity” to raise the “impending prospects of germline genetic or other eugenic practices.”¹⁹⁶ As one assessed:

¹⁹³Soh, *supra* note 160.

¹⁹⁴Brave, *supra* note 19.

¹⁹⁵Smith, *supra* note 31, at 103.

¹⁹⁶Brave, *supra* note 19.

Kass invoked the brave new world image to recommend a ban on embryo cloning, even cloning for research purposes... [the] political calculation, explicitly expounded by Kass and others, is that by focusing on as unpopular a prospect as human cloning, they can seize control of critical portions of the biomedical agenda, constrict its inquiries, alter the pace of biotech developments and provide a cautionary pause during which more extensive, global prohibitions can be put into place.¹⁹⁷

Kass' position may not be wrong, but public opinion must be shaped by facts, rather than intentionally distorted scenarios. As one writer comments, "[I]t seems unlikely that cloning will be used by dictators to perpetuate themselves, or to produce a warrior class to serve the purposes of the state or their own demented ends. Our most farfetched fears should not drive policy making."¹⁹⁸

Experience shows that greater public awareness can moderate sensationalism. As discussed above, the openness of the RAC contributed to the transition from alarmist thinking about an "Andromeda strain" to general acceptance of gene therapy. In Singapore, the plan to develop biomedical research guidelines includes a series of public forums intended to inform the public and thereby prevent dialogue from being "dictated by sensationalism and worst-case premises."¹⁹⁹

Although it is nearly impossible to define what it means for the general public to be sufficiently informed, it is possible to set certain parameters. For example, it would be unnecessary for the average American to be conversant in the intricate technical details of cloning procedures, but it would be desirable for the average American to be aware of three or four basic distinctions between therapeutic and reproductive cloning. The AGTC is not obligated to transform all Americans into scientists, but part of its job should be to distill essential scientific background information into plain-language explanations which are comprehensible to non-scientists.

Furthermore, the AGTC should explore ways of reaching the public with this information. At a minimum, the AGTC can post this information on a website and establish working relationships with major media

¹⁹⁸Solomon, *supra* note 121, at 660.

¹⁹⁹Soh, *supra* note 160, quoting the director of medical services at the Singapore Ministry of Health.

organizations; however, the AGTC should also explore more creative methods, e.g., offering these materials to schools for integration into classroom discussion, sponsoring public service announcements. At the same time, the AGTC must handle its public education role with care. In its diligent efforts to inform the public, the AGTC must be careful to avoid the perception that it is promoting a particular point of view.

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The AGTC shall also be the United States' liaison with the international community on bioethics issues. As discussed above, concerted international action may be necessary to proscribe certain practices effectively, and the United States is in a position to play a unique role in any global regulatory effort. Aside from any leadership obligation, however, it would be valuable for the AGTC to monitor what is happening internationally because other countries' actions offer a perspective on steps that might be appropriate domestically. For example, a survey of cloning policies around the world demonstrates that other nations have acted more quickly than the United States in banning human reproductive cloning. The United Kingdom was early to prohibit the practice,²⁰⁰ and since then many other European countries have endorsed a Council of Europe treaty which bans "any intervention seeking to create a human being genetically identical to another human being, whether living or dead."²⁰¹ Viewing this treaty as too lax, Germany abides by a stricter measure which bans research on all human embryos.²⁰² Outside of Europe, Israel established a five-year ban on human cloning at the end of 1998. Japan has also banned human cloning and has taken the additional step of establishing a special committee to regulate research which involves techniques that border on human

²⁰⁰Human cloning prohibitions were included in the 1990 Human Fertilisation and Embryology Act.

²⁰¹36 I.L.M. 1415 (1997), *Council of Europe: Draft Additional Protocol to the Convention on Human Rights and Biomedicine on the Prohibition of Cloning Human Beings*. Signatories include Denmark, Estonia, Finland, France, Greece, Iceland, Italy, Latvia, Luxembourg, Macedonia, Moldova, Norway, Portugal, Romania, San Marino, Slovenia, Spain, Sweden, and Turkey.

²⁰²Greene, *supra* note 29, at 354. Germany's strict policy may reflect the legacy of Nazi eugenic efforts.

cloning.

Most countries tend to be more permissive toward stem cell research. The United Kingdom recently liberalized its strict regulations to permit the development and use of stem cells from human embryos. This change in policy was motivated by the desire not to hamper research which could lead to better treatments for many serious diseases.²⁰³ Elsewhere in Europe, the Council of Europe treaty mentioned above does not rule out stem cell research, and Sweden and Finland allow research on embryos up to 22 days old. India and China have no restrictions at all. In contrast, embryonic stem cell research is prohibited in Ireland, where an unborn child is considered to be constitutionally equivalent to its mother.²⁰⁴ Brazil and most Latin American countries have also banned it, and France and Germany currently do not allow it but are in the process of reconsidering their laws.²⁰⁵

As this brief overview indicates, other nations' bioethical policies are heterogeneous and fluid, and changes are inevitable as science continues to advance. China, for example, already anticipates that some regulation may be necessary. According to a spokesman at the Ministry of Science and Technology, "We hope that our scientists will make breakthroughs in their research. But we don't want to see any negative impact that could result from rushing forward blindly... The government is considering new laws, but it isn't clear when they might be enacted."²⁰⁶ The AGTC is the logical place to track developments in international regulations, assess any implications for the United States' domestic policies, and represent the United States in global bioethics discussions.

²⁰³In the U.K., the regulation of stem cell research has grown from the regulatory framework for assisted reproductive technologies. There are two government organizations with jurisdiction over this area: The Human Fertilisation and Embryology Authority (HFEA), which oversees developments in fertilization and genetic procedures; and The Human Genetics Advisory Commission (HGAC), a government-sponsored think-tank. When the Human Fertilization and Embryology Act was initially passed, therapeutic cloning was not considered to be an acceptable purpose for embryo research. As science advanced, HFEA and HGAC revisited the policy and after extensive debate, recommended that Parliament vote to allow the cloning of human embryos for the derivation of stem cells. *See* Knowles, *supra* note 94, at 20-21.

²⁰⁴*The Stem Cell Debate*, *supra* note 103.

²⁰⁵*Id.*

²⁰⁶Leggett and Regalado, *supra* note 16.

Conclusion

The time has come to establish a permanent government institution dedicated to bioethics issues. This call is not new; in fact, a similar call was voiced as long ago as the early 1980s.²⁰⁷ Now, however, the time has *really* come. The remarkable, swift progress of biomedical science promises to improve human life in unprecedented ways, but it also raises moral and philosophical questions of unprecedented difficulty. Events during the last five years, from the cloning of Dolly to the debate over embryonic stem cell research, have provided a glimpse of how contentious these bioethical issues can be, and the efforts to address these developments have been fragmented, reactive, and generally ineffective. Before the wave of “genomic power and knowledge”²⁰⁸ arrives in earnest, these bioethical issues must be considered and addressed in a systematic, proactive, and effective way.

The AGTC is an institution which would do so. Its structure, capabilities, and responsibilities are designed to facilitate the development and implementation of sensible and consensus-based policies. Although the strength of market forces, the relentless progress of science, and the heterogeneity of moral views will make ethical control of biotechnology very challenging, it is possible. The establishment of a (long over)due process for the development of bioethics policy is the crucial first step toward meeting this challenge.

²⁰⁷OTA report, *supra* note 152, at 25.

²⁰⁸*See supra* note 146.